

University of Maryland, College Park

Human Research Protections

Policies and Procedures

October 9, 2020

Table of Contents

POLICY #	POLICY AND PROCEDURE	PAGE #
1.001	The Institution and its Commitment to the HRPP	4
1.002	Federal Wide Assurance	5
1.003	Vision, Mission, and Values Statement of UMCP	7
1.004	Vision, Mission, and Values Statement for the HRPP	9
1.005	IRB Charter, Appointments, and Administrative Structure	10
1.006	Authority Granted by UMCP to the IRB Operating in the HRPP	12
2.001	IRB Membership Requirements and Responsibilities	14
2.002	IRB Meetings and IRB Member Responsibilities	18
2.003	IRB Consultants	20
2.004	Orientation and Initial Training for New IRB Members and HRPP Staff	22
2.005	IRB Member Conflict of Interest Management	23
2.006	Continuing Education Requirements for IRB Members and HRPP Staff	26
2.007	Evaluation of IRB Members	28
2.008	IRB Member Confidentiality	30
2.009	IRB Reviewer Assignment	31
2.010	IRB Member Reviews and Development of the IRB Determination Letter	34
2.011	IRB Quorum and Voting Requirements	36
2.012	IRB Minutes	38
2.013	HRPP Policy Review and Approval	42
2.014	IRB Records	44
3.001	Investigational Activities Requiring IRB Review and Approval	49
3.002	Ethical Principals Governing Research under Jurisdiction of the IRB	55
3.003	Initial Application Submission	57
3.004	Criteria for IRB Approval of Research	59
3.005	IRB Initial Review Categories	69
3.006	Scientific and Scholarly Merit Review of Projects	73
3.007	Conflict of Interest Review by IRB and Office of Research Administration	76
3.008	Qualification and Responsibilities of Research Personnel	80
3.009	Required Training in the Protection of Human Participants	82
3.010	Interim Review, Monitoring, and Verification of Outside Sources	85
3.011	Certificate of Confidentiality	87
3.012	External IRB Approval of Cooperative Research	90
3.013	Research Records Retention and Security	92
3.014	PI Disagreements with IRB Determinations	94

POLICY #	POLICY AND PROCEDURE	PAGE #
3.015	Compensation for Research Participants	96
3.016	Recruitment of Participants through Advertisements	99
4.001	Exempt Research	102
4.002	Expedited Research	109
5.001	Additional Protections for Vulnerable Populations	115
5.002	Research Involving Pregnant Women, Human Fetuses, and Neonates	118
5.003	Research Involving Prisoners	124
5.004	Research Involving Children	133
5.005	Research Involving Decisionally Impaired Participants	146
5.006	Research Involving Employees and/or Students	150
6.001	Certification of Review Funding	152
7.001	Quality Improvement Assessment	153
8.001	Students as Researchers	157
8.002	Epidemiological Research Guidelines	162
8.003	Exercise Project Guidelines	167
8.004	Research Conducted in Foreign Countries	170
8.005	Community-Based Preparatory Research	172
9.001	Required Elements for Informed Consent Documents	174
9.002	Development of the Informed Consent Document	182
9.003	Verbal/Telephone Consent	186
9.004	Re-Consent/Assent Research Participants	189
9.005	Absence of Valid Consent: Re-Consent and Use of Data	191
9.006	Waiver or Alteration of Consent	192
10.001	Protected Health Information Identifiers	195
10.002	Limited Data Set	197
10.003	Research Utilizing Medical Records	198
10.004	Review of Protected Health Information in Preparation for Research	202
11.001	Continuing Review	203
11.002	Suspension and Termination	212
12.001	Request for Change – Amendments	214
13.001	Reportable Events	217
14.001	Noncompliance	222
14.002	Reporting Incidents to OHRP or Department and Agency Heads	228
14.003	Audits by Outside Agencies	231
15.001	Human Research Compliance: Department of Education	234
15.002	Human Research Compliance: Environmental Protection Agency	237

POLICY #	POLICY AND PROCEDURE	PAGE #
15.003	Human Research Compliance: Department of Justice	239
15.004	Human Research Compliance: Department of Defense	242
15.005	Human Research Compliance: Department of Energy	246
16.001	Conflicts of Interest Management	248
16.002	Institutional Conflicts of Interest	249

Abbreviations

ABBREVIATION	FULL FORM
AE	Adverse Event
AAHRPP	Association for the Accreditation of Human Research Protection Programs
CFR	Code of Federal Regulations
CITI	Collaborative Institutional Training Initiative
COI	Conflicts of Interest
COIR	Conflicts of Interest in Research
COIRC	Conflicts of Interest in Research Committee
DHHS	Department of Health and Human Services
FCOI	Financial Conflicts of Interest
FTE	Full Time Equivalent
FWA	Federal Wide Assurance
HIPAA	Health Insurance Portability and Accountability Act
IBC	Institutional Biosafety Committee
IO	Institutional Official
IRB	Institutional Review Board
OHRP	Office of Human Research Protections
PI	Principal Investigator
PRIM&R	Public Responsibility in Medicine and Research
RSC	Radiation Safety Committee
SOP	Standard Operating Procedure
UMCP	University of Maryland, College Park



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 1.001

Title: The Institution and Its Commitment to the HRPP

Section: *Organizational Commitment to HRPP*

Date: December 5, 2017 **Reviewed:** January 28, 2020

1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the Institution and the commitment to the Human Research Protections Program (HRPP).

2.1 Policy

The Institution is committed to the human participant research protection program through establishment and funding of an Institutional Review Board (IRB) operating in full compliance with Health and Human Services regulations at 45 CFR §46.

2.2 The Institution is comprised of:

A. The University of Maryland College Park (UMCP)

2.3 The Institution is committed to ensuring the existence and evolution of premier educational programs, high quality research, which is conducted with integrity, consistent with ethical standards, and with respect for all individuals and groups (HRPP Policies [1.004](#) and [2.001](#))

2.4 The IRB has been authorized by the Institutional Official to review and approve all human participant research conducted by the faculty, students, staff, or other Institutional representatives regardless of where the research is conducted, unless the IRB accepts the review and approval of another duly constituted IRB.

2.5 UMCP may conduct FDA regulated research.

A. If UMCP does conduct FDA regulated research; the UMCP IRB will ensure appropriate expertise is present to review the research. If the UMCP IRB does not have appropriate expertise to review the FDA regulated research, it will not conduct the review.



1.0 Purpose

The Purpose of this SOP is to describe the agreement with the Department of Health and Human Services Office of Human Research Protection (OHRP) through the FWA.

2.1 Policy

It is the policy of the IRB that this Institution will file and maintain an agreement with OHRP through a FWA. This Institution has declared that all institutional components listed under the **UMCP FWA (#00005856)** must comply with this assurance.

- 2.2** The Institution has determined that *all* human participant research will be governed by the Health and Human Services regulations at 45 CFR §46 and ethical standards regardless of funding source.
- 2.3** The Institution has determined that all of its activities related to human participant research, regardless of funding source, will be guided by the ethical principles found in the Belmont Report.
- 2.4** The Institution has designated establishment and registration of one IRB with provisions for sufficient meeting space and staff to support the IRB's review and recordkeeping duties (HRPP Policies [1.005](#) and [2.003](#)).
- A. IRB-01 (IRB00000474 – University of Maryland College Park – IRB#1)**
- 2.5** The Institution will maintain a list of IRB members identified by name, earned degree, representative capacity, as well as maintenance of current curriculum vitae for each IRB member. Changes in IRB memberships will be reported to OHRP through filing an IRB Registration Update.
- 2.6** The Institution has established HRPP written policies and procedures as required under Health and Human Services regulations at 45 CFR §46.103.
- A.** The IRB will conduct initial and continuing review of research (at intervals appropriate to the degree of risk, but not less than once per year). The investigator and the Institution will be provided written notification of the findings and actions taken by the IRB (HRPP Policies: [3.002](#), [3.003](#), [3.004](#), [3.005](#), and [11.001](#)). The IRB will determine



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 1.002

Title: Federal Wide Assurance

Section: *Organizational Commitment to HRPP*

Date: December 5, 2017

Reviewed: January 28, 2020

which projects require review more often than annually (HRPP Policy #[3.010](#)) and which projects require verification from sources other than the investigators that no material changes have occurred since the previous IRB review.

- B. The IRB shall ensure that proposed changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate immediate risk to the participant (HRPP Policies: [12.001](#), [13.001](#) and [14.001](#)).
- C. The IRB shall have the authority to observe, or have a third party observe, the consent process and the research.
- D. The IRB shall ensure prompt reporting to the IRB, appropriate institutional officials, and federal regulatory officials (OHRP, National Science Foundation, and other department or agency heads) (HRPP Policy #[14.002](#)):
 - 1. All incidences of unanticipated problems involving risk to participants or others
 - 2. Any serious or continuing noncompliance with federal or IRB requirements
 - 3. Suspension or termination of IRB Approval
- E. The IRB shall require confirmation by a qualified person, other than study personnel that research proposal qualifies for Exempt status (HRPP Policy #[4.001](#))



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 1.003

Title: Vision, Mission, and Values Statement of UMCP

Section: *Organizational Commitment to HRPP*

Date: December 5, 2017

Revised: July 31, 2020

1.0 Purpose

The purpose of this SOP is to describe the vision, mission, and values for UMCP.

2.1 Policy

UMCP has developed a comprehensive vision, mission, and values statement.

2.2 Vision

During the next decade, the University of Maryland will enhance its standing as a world-class, preeminent institution of higher education.

The University will achieve this goal through an unwavering commitment to excellence in all that it undertakes.

The University will attract a diverse student body that possesses the ability and passion for learning. Innovative and relevant programs, whether within or built upon traditional disciplines in the arts and sciences, will prepare students to be engaged and self-realized citizens and leaders in a complex, democratic society.

The University will foster research, scholarship, and arts programs noted for their quality, creativity, and impact, and provide affordable access.

As befits its proximity to the nation's capital, the University will expand its international influence and address great and challenging problems of our time. Taking maximum advantage of its special location, the University will be a world center for creation and refinement of knowledge; advancement in science and technology, humanities, and social sciences; global leadership; and innovative production in the creative and performing arts.

2.3 Mission Summary

Achieving excellence in teaching, research, and public service within a supportive, respectful and inclusive environment is central to the mission and identity of the University of Maryland, College Park (UMD). As the flagship campus and a national leader in higher education, UMD strives to provide exceptional and affordable instruction for Maryland's most promising students, regardless of income. A pre-eminent locus of scholarship, the university builds and maintains a world class capacity in the sciences, arts, and humanities to support ground-breaking discoveries that address the most pressing global challenges and inspire the human imagination. As one of the country's first land-grant institutions, UMD uses its research, educational, cultural, and technological strengths in partnership with state, federal, private, and non-profit sectors to promote economic development and improve quality of life in the State of Maryland. Diversity amongst our students, faculty and



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 1.003

Title: Vision, Mission, and Values Statement of **UMCP**

Section: *Organizational Commitment to HRPP*

Date: December 5, 2017

Revised: July 31, 2020

staff is essential to this mission. Accordingly, ensuring equal educational opportunity; hiring and retaining a diverse and exceptional faculty and staff; recruiting and graduating talented students from traditionally underrepresented groups; and providing a supportive climate for their well-being are top institutional priorities.

The full Mission Statement can be viewed here: <https://svp.umd.edu/mission-vision>



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 1.004

Title: Vision, Mission, and Values Statement of HRPP

Section: *Organizational Commitment to HRPP*

Date: December 5, 2017

Reviewed: July 31, 2020

1.0 Purpose

The purpose of this SOP is to describe the vision, mission, and values for the HRPP.

2.1 Policy

The IRB has developed a comprehensive vision, mission, and values statement.

2.2 Vision

The HRPP for UMCP, hereafter referred to as the “Institution” and affiliates, will be a nationally known HRPP where:

- A. Investigators will conduct research with the highest thought, technical skill, and care.
- B. Investigators will adhere to high standards of research ethics, comply with all applicable federal, state, and local laws and regulations, and always consider the rights and welfare of research participants.
- C. IRB Members and Staff will keep abreast of the latest developments in the ethics and regulation of human participant research and will perform thorough and consistent review of research projects.

2.3 Mission

The mission of the HRPP is to ensure the protection of human participants who choose to participate in research conducted by investigators at the Institution and affiliates that is part of a broader framework of the responsible conduct of research.

2.4 Values

- A. Faculty, staff, students, and others who serve as investigators will emphasize the conduct of quality research, which is carried out with scientific integrity and in an ethical manner.
- B. Investigators will respect all individuals and groups served by this institution.



1.0 Purpose

The purpose of this SOP is to describe the IRB charter, appointments, and administrative structure.

2.1 Policy

It is the policy of the IRB that the structure and composition of the IRB be in full accordance with the Health and Human Services policies and 45 CFR §46.

2.2 IRB Charter

The UMCP IRB is a duly constituted IRB, which has established membership in full accordance with the requirements of Health and Human Services regulations at 45 CFR §46.107.

2.3 Institutional Official

The President has appointed the Vice President for Research to serve as the Institutional Official (IO) in accordance with the provisions of the **Federal Wide Assurance (FWA #00005856)**. The IO appoints the officers of the IRB and all IRB Members.

2.4 HRPP Director

HRPP Director (Director) reports to the IO, including on matters concerning compliance with 45 CFR §46 and HRPP policies and procedures. The IO has delegated responsibility for the daily operation of the HRPP to the Director who has a continuous appointment. The Director is primarily involved in the development of HRPP policies and procedures, revision of IRB forms, compliance issues, conflict resolution, and continuing education of both IRB members and investigators.

2.5 IRB Chair

The IRB Chair works closely with the Director and the IRB Co-Chair (if needed). The IRB Chair is primarily involved in conducting IRB meetings, reviewing projects, as needed, reviewing adverse events and serious problems, continuing education of IRB members and investigators, development of policies, procedures, and IRB forms, and serves as a resource



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 1.005

Title: IRB Charter, Appointments, and Administrative Structure

Section: *Organizational Commitment to HRPP*

Date: December 5, 2017

Reviewed: July 31, 2020

for investigators and IRB members regarding issues related to the University and federal policies. The Chair reviews and approves *expedited* initial, continuing review, and amendment applications. The IRB Chair's term of service is at the discretion of the IO. The IRB Chair and Co-Chair (if needed) has a direct line to the IO and the President as necessary.

2.6 Research Compliance Office

The HRPP within the Research Compliance Office serves as the administrative office for the IRB. Research Compliance Analysts, Research Compliance Office Administrative Assistants and IRB Graduate Assistants are hired and operate under the direction of the Director.

2.7 Administrative Structure

The IRB has direct access to the HRPP Director, IO, and President.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 1.006

Title: Authority Granted by UMCP to the IRB
Operating in the HRPP

Section: *Organizational Commitment to HRPP*

Date: December 5, 2017

Revised: July 31, 2020

1.0 Purpose

The purpose of this SOP is to describe the authority granted by UMCP to the IRB operating in the HRPP.

2.1 Policy

It is the policy of the IRB that the Institution provide sufficient resources and decisional autonomy for the IRB to carry out its duties independently of the Institution in full accordance with Health and Human Services policies at 45 CFR §46.

2.2 UMCP through its President, authorizes the IRB to independently review and approve all human participant research conducted or supported by the faculty, students, staff, or other representatives of UMCP, when such research is part of their institutional responsibilities regardless of where the research is conducted unless the IRB accepts the review and approval of another duly constituted IRB with a FWA for research conducted at other study sites.

2.3 The Vice President for Research will serve as the IO.

2.4 The IRB, which is housed administratively within the Division of Research's Research Compliance Office, shall exercise its authority in full accordance with Health and Human Services regulations at 45 CFR §46 and HRPP policies and procedures. This authority includes review and approval of *exempt* research under 45 CFR §46.104; research which qualifies for *expedited review* under 45 CFR §46.110; and research, which requires review by the fully convened IRB. The IRB has the empowerment, flexibility and discretion to raise the standards of protection above those afforded to research participants in 45 CFR §46 as it deems appropriate and necessary in particular cases although it may not lower the protections below those afforded by 45 CFR §46.

2.5 IRB members are to report any attempts to unduly influence their decisions to the IRB Chair, the HRRP Director, or the Vice President for Research. The IRB Chair, in consultation with the HRPP Director



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 1.006

Title: Authority Granted by UMCP to the IRB
Operating in the HRPP

Section: *Organizational Commitment to HRPP*

Date: December 5, 2017

Revised: July 31, 2020

and the Vice President for Research, will investigate the allegations, and if true, will take any needed corrective action.

- 2.6** The Institution will apply 45 CFR §46, including Subpart A, B, C, and D, to all human participant research regardless of funding, with the exceptions noted in HRPP Policy #[5.003](#), Section 2.3 for Subpart C. Subpart B is intended to apply to all human participant research including that performed in the social and behavioral sciences as noted in HRPP Policy #[5.002](#), Section 2.2.
- A.** UMCP does not conduct research involving investigational test articles. Human research that would fall under the purview of the FDA may be reviewed at UMCP if appropriate expertise can be found to serve on the IRB. If the UMCP IRB does not have appropriate expertise to review the FDA regulated research, it will not conduct the review.
- 2.7** Per Health and Human Services regulations at 45 CFR §46.112 the institution acknowledges that research, which has been approved by the IRB, may be subject to further appropriate review by the IO, or his/her designee. However, no official may approve research if it has not been approved by the IRB. In addition, any attempt to unduly influence the IRB from both within and outside the Institution is strictly prohibited and must be reported to the IO or the President who will take appropriate action.
- 2.8** Approval of research by the IRB can be overturned by the IO or his/her designee. The reasons for administrative disapproval of research by the IO or his/her designee shall be provided in writing to the IRB. The IRB will notify the Principal Investigator (PI) of any disapproval in writing and provide the reason(s) for disapproval.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.001

Title: IRB Membership Requirements and Responsibilities

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: August 24, 2020

1.0 Purpose

The purpose of this SOP is to describe the IRB membership requirements and responsibilities.

2.1 Policy

It is the policy of UMCP that the IRB will include an appropriately diverse mixture of backgrounds and experiences in accordance with the Health and Human Services regulations under 45 CFR §46.107. The IRB will adhere to the following policy:

- 2.2** The IRB will have at least five (5) members. Members will be appointed for revolving one year terms.
- 2.3** Members will represent varying academic disciplines and have the necessary credentials to provide appropriate review of projects submitted for review. The IRB will represent the diversity of the community in order to provide guidance on varying perspectives and sensitivities. The IRB will be sufficiently qualified through experience, expertise, and diversity to provide appropriate review of research with a primary focus on protection of human participants.
- 2.4** The IRB will include at least one member that is not affiliated with the Institution. The unaffiliated member must not: 1) have a professional relationship with the Institution as an employee, consultant, volunteer faculty, or student, and 2) be a family member (first and second degree relative), which has a professional relationship with the Institution.
- 2.5** The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- 2.6** The IRB will have a non-voting representative from the University's General Counsel Office serving in an *ex officio* capacity to offer legal counsel to the Board.
 - A.** When legal conflicts arise, the counsel to the IRB will provide a legal opinion and resolution to the IRB.
- 2.7** The IRB will include one or more members who are knowledgeable about, and experienced in, working with vulnerable participants, including: children, prisoners, people with disabilities or cognitively impaired individuals.



**Human Research Protections
Policies and Procedures**

Research Compliance Office
Institutional Review Board

Policy #: 2.001

Title: IRB Membership Requirements and Responsibilities

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: August 24, 2020

- 2.8** In situations where a prisoner is involved in research under IRB review and the Board does not already have a member with appropriate background and experience to serve in the capacity of prisoner representative, the Board will include an ad-hoc prisoner representative to serve in that capacity. This individual must have a close working knowledge, understanding, and appreciation of the prison conditions in the facility where the research will be conducted from the perspective of the prisoner.
- 2.9** Where members have conflicts of interest pertaining to the research to be reviewed, members must be absent themselves from the meeting room before the final review discussion and vote, except where requested by the IRB to be present to provide information. IRB members with conflicts of interest must not participate in all types of reviews, including initial review, continuing review, review of modifications, review of unanticipated problems involving risks to participants or others, and review of non-compliance. IRB members also may not serve as reviewers for research in which they have a conflicting interest when asked to review using the expedited review process.
- 2.10** When review of a proposal requires expertise that is not available on the Board, at its discretion, the IRB will request assistance from an expert consultant. These individuals have access to all documents submitted to the IRB relevant to the specific project under review and may participate at the deliberations and make recommendations on the project, but will not vote (HRPP Policy #[2.003](#)).
- 2.11** Alternates are appointed and function in the same manner as the primary IRB members. The alternate's expertise is comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the primary member is unable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received.
- 2.12** The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.



**Human Research Protections
Policies and Procedures**

Research Compliance Office
Institutional Review Board

Policy #: 2.001

Title: IRB Membership Requirements and Responsibilities

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: August 24, 2020

- 2.13** IRB members are expected to be fully engaged in the HRPP and will be involved in carrying out the following responsibilities (when requested by the IRB Chair or designee):
- A.** Serving as a primary or secondary reviewer for initial applications.
 - B.** Serving as a primary or secondary reviewer for continuing review applications.
 - C.** Serving as a primary or secondary reviewer for internal unanticipated problems involving risk to participants or others.
 - D.** Serving as a primary reviewer for external adverse events or serious problems.
 - E.** Serving as a primary or secondary reviewer for amendments/ modifications to projects and/or consent documents.
 - F.** Serving as a primary reviewer for incidents of non-compliance.
 - G.** Serving as an expedited reviewer.
 - H.** Acknowledging protocol deviations.
 - I.** Completing continuing education.
- 2.14** When the IRB membership changes, the IRB Manager will prepare the notice that will be submitted by the IO or designee to the OHRP within (30) business days.
- 2.15** A membership list of IRB members must be maintained; it must identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list must contain the following information about members:
- A.** Name
 - B.** Earned degrees
 - C.** Affiliated or non-affiliated status



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.001

Title: IRB Membership Requirements and Responsibilities

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: August 24, 2020

- D. Status as scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist). For the purposes of this roster, IRB members with research experience are designated as scientists (including graduate student members). Research experience includes training in research (e.g. doctoral degrees with a research-based thesis) and previous or current conduct of research. Graduate students being trained in research fields will be designated as scientists.
- E. Indications of experience, such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations.
- F. Representative capacities of each IRB member, which IRB member is a prisoner representative (as required by Subpart C), and which IRB members are knowledgeable about or experienced with working with children, pregnant women, decisionally-impaired individuals, and other vulnerable populations locally involved in research.
- G. Role on the IRB (Chair, Vice-Chair, etc.)
- H. Voting status (any ex-officio members are non-voting members).
- I. Alternate status, including the member they alternate with.
- J. Relationship (e.g. employment) between the individual IRB member and the organization.

2.16 The IRB roster is confidential. The names of IRB members who reviewed specific projects will not be released.



1.0 Purpose

The purpose of this SOP is to describe the structure of IRB meetings and IRB member responsibilities.

2.1 Policy

It is policy of the IRB that the structure of IRB meetings and responsibilities of IRB members are clearly defined.

2.2 IRB meeting dates are determined at the end of each calendar year.

2.3 Three (3) weeks prior to the scheduled IRB meeting, an Analyst sends RSVP email to each board member requesting their attendance. The members are officially notified of the date, time, and location of the IRB meeting. This information can also be found on the secure online website (IRBNet).

2.4 Ten (10) to fourteen (14) days prior to the IRB meeting, IRB applications and supporting materials will be posted on IRBNet for IRB members to access, review, and provide written feedback.

A. For initial reviews by a convened IRB, all members are provided with:

- 1.** The full protocol or a project summary containing the relevant information needed to determine whether the proposed research fulfilled the criteria for approval.
- 2.** Proposed consent document.
- 3.** Recruitment materials.
- 4.** The DHHS-approved protocol (when one exists).

B. Primary and secondary reviewers perform an in-depth review of all pertinent documentation. All other IRB members review all provided materials in enough depth to discuss the information at the convened meeting. When conducting reviews using the expedited process, the reviewer has access to and reviews all submitted information including, at a minimum, all information the convened IRB would have received.

2.5 The IRB has a minimum of five (5) regular voting members, plus one (1) non-voting ex-officio member serving as a legal representative.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.002

Title: IRB Meetings and IRB Member Responsibilities

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: August 24, 2020

- 2.6** A quorum will be established in accordance with federal requirements. If quorum is not met or is lost, the meeting will be postponed and re-convened as soon as possible (HRPP Policy [#2.011](#)).
- A.** **Quorum** is defined as the minimum number of IRB members that must be present at the IRB Meeting to make an action/vote valid. A majority must be present. For example, if 14 members are on the IRB Member roster, quorum is defined as 8 voting members present at the IRB Meeting (inclusive of at least one non-scientist member).
- 2.7** IRB members will serve as primary or secondary reviewers. A primary and secondary review will be assigned to all initial reviews and tabled reviews. A primary reviewer will be assigned to amendment and continuing reviews.
- 2.8** Members will review and vote on IRB policies as required (HRPP Policy [#2.013](#)).
- 2.9** Persons may be invited to attend IRB meetings as guests under the following conditions:
- A.** Guest attendance is at the discretion of the IRB Chair.
- B.** Guests may be asked to leave at any time.
- C.** Guests will be asked to state the purpose of their visit.
- D.** Guests attending a meeting where a proposed project has been submitted will be asked to provide information about a proposed study and answer any question the IRB may have regarding the project under review.
- E.** All requests for visitors to attend an IRB meeting must be directed to the IRB Chair. The request must include the name(s) of the visitors, the rationale for the visit, and the proposed visit date. The request will be discussed at the next IRB meeting. If the IRB approves the request, the visitor will be scheduled to attend an IRB meeting in the future.
- F.** If the request is granted, the visitor will be required to sign a Confidentiality Agreement and may be required to leave the room during any discussion as necessary.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 2.003

Title: IRB Consultants

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: August 24, 2020

1.0 Purpose

The purpose of this SOP is to describe the identification, appointment, and role of the IRB consultants.

2.1 Policy

It is the policy of the IRB that services of expert consultants will be obtained as needed.

2.2 Either before or during the review of a protocol, the IRB Chair, assigned IRB reviewer, or the IRB itself, will determine if there is a need for appointment of an expert consultant, either a scientist or a non-scientist, in accordance with the provisions of 45 CFR §46.107(f). Depending upon the nature and magnitude of the problem or concern, the IRB may seek more than (1) consultant.

2.3 Consultants will be selected from within the Institution, as well as from outside the Institution based upon the required expertise.

A. The IRB Chair will table a project to another meeting, or obtain consultation if there is not appropriate scientific, scholarly, or representational expertise.

2.4 Consultants will sign a Confidentiality Agreement prior to reviewing any project or receiving detailed information regarding the project in question.

2.5 Consultants generally will produce written reviews and they may participate in the IRB's discussion of the project.

2.6 Written reviews will be accessible to all IRB reviewers.

2.7 Consultants who attend an IRB meeting may not vote and are excused upon conclusion of discussion of the project in question.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.003

Title: IRB Consultants

Section: *IRB Membership & Standard Operating
Procedures*

Date: December 5, 2017

Reviewed: August 24, 2020

- 2.8** Potential consultants will be queried and asked to sign an attestation by the IRB Chair before the meeting as to whether they have any potential conflicts of interest¹ with the relevant investigators or funding agencies. If they do, they will be excused and another consultant found.
- 2.9** When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the IRB Chair or Director will ensure that one or more individuals who are knowledgeable about, or experienced in, working with such participants will be present at the meeting.

¹ Conflicts of interest shall mean situations where a consultant's direct or indirect interests (financial or otherwise) may compromise, or have the appearance of compromising, the consultant's professional judgment or behavior in carrying out his or her obligations to the University of Maryland College Park IRB.



1.0 Purpose

The purpose of this SOP is to describe the orientation and initial training for new IRB members and Human Research Protections Program (HRPP) staff.

2.1 Policy

It is the policy of the IRB to provide new IRB members and HRPP staff with an orientation and initial training that includes the information necessary to facilitate the performance of assigned responsibilities.

2.2 All new IRB members and HRPP staff must complete a two (2) hour new member orientation. The orientation is conducted by the IRB Chair and/or the Director or IRB Manager. HRPP policies and procedures are reviewed and explained and OHRP training videos are shown.

2.3 The Orientation Packet includes the following materials:

- A. IRB Membership Roster
- B. Code of Federal Regulations: 45 CFR §46
- C. The Belmont Report
- D. Federal Wide Assurance (FWA 00005856)
- E. HRPP Policies and Procedures
- F. All current UMCP IRB Forms
- G. Copy of the IRB Member Handbook by R. Amdur

2.4 All IRB members and staff are required to complete CITI (Collaborative Institutional Training Initiative) Training: www.citiprogram.org. IRB Members are required to complete the IRB Member Training Modules and HRPP Staff are required to complete the Biomedical or Social and Behavioral Research – Basic Modules. A minimum passing score of 80% is required to obtain CITI certification. HRPP staff is also required to complete the COI Mini Course, Responsible Conduct of Research Course and are encouraged to complete any optional courses that are available.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 2.005

Title: IRB Member Conflict of Interest Management

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: August 24, 2020

1.0 Purpose

The purpose of this SOP is to describe the identification and management of IRB member conflict of interest.

2.1 Policy

It is policy of the IRB to identify and appropriately manage all IRB member potential conflicts of interest.

- 2.2** Upon receipt of IRB meeting materials, all IRB members must notify the IRB Chair or Vice Chair of a conflict of interest in advance of the upcoming meeting or upon assignment as an expedited, primary, or secondary reviewer. If the IRB member is uncertain if a potential conflict of interest exists, they are encouraged to consult with the IRB Chair or Director.
- 2.3** Prior to the beginning of each meeting, IRB members will be asked to declare, but are not required to describe, any conflict of interest related to the protocols under review, which already have not been declared.
- 2.4** The individual can be a member of the IRB; however, he/she cannot participate in the review and approval process for any project in which he/she has a conflict of interest, the IRB protocol is reassigned to another reviewer. When the member has a conflicting interest, he/she will not be present during final discussion and vote and may be present only at the beginning of the meeting to provide information if requested by the IRB. He/she must be absent from the meeting room during the subsequent discussion and voting phases of the review and may not participate in the vote. The absent member is not counted towards a quorum when the vote on the protocol in question is taken. The IRB Meeting Minutes will reflect whether or not these requirements have been met.
- 2.5** The following constitutes IRB member conflict of interest:
 - A.** The IRB member (or an immediate family member, as defined below) serves as a Principal Investigator (PI) and is, accordingly, listed on the IRB application, or has served as a scientific advisor to the PI.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.005

Title: IRB Member Conflict of Interest Management

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: August 24, 2020

1. Immediate family member: parent(s), or spouse of a parent, spouse, biological or adopted child, or anyone that may be claimed as a dependent under the Internal Revenue Code.
- B. The IRB member (or an immediate family member) is an advisor (e.g. thesis/dissertation committee member) or a direct supervisor of trainee's (e.g. graduate or undergraduate student) research.
 - C. The IRB member (or an immediate family member) has received payments in excess of \$0 including salary, consulting fees, royalty, or licensing payments from intellectual property, honoraria and/or gifts from the commercial company sponsoring the research, or their representative(s) or with a company with a financial interest in the product or service being tested over the past 12 months or anticipates receiving such payments during the next 12 months.
 - D. The IRB member (or an immediate family member) has equity interest in the commercial company sponsoring the research or in the product or service being tested, which is worth more than \$0.
 - E. The IRB member (or an immediate family member) holds a paid or unpaid position as director, officer, partner, trustee, or any other significant position (e.g. scientific advisory board/consultant) in the company sponsoring the research or with a company with a financial interest in the product or service being tested.
 - F. The IRB member (or an immediate family member) holds patent rights or royalties from such rights whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving UMCP.
 - G. The IRB member (or an immediate family member) has a financial interest (as defined above in items C, D, E, or F) in a company, which has a marketed product, or is in the process of developing a new product, which is, or will be, in direct market competition with the product in the project under IRB review.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.005

Title: IRB Member Conflict of Interest Management

Section: *IRB Membership & Standard Operating
Procedures*

Date: December 5, 2017

Reviewed: August 24, 2020

- H. The IRB member (or an immediate family member) has a personal relationship, or a conflict, with any investigator(s) listed on the IRB application, which would potentially cause the IRB member to be perceived as less than objective in his/her review.
- I. The IRB member (or an immediate family member) has an ownership interest or compensation related to the research whose value may be affected by the outcome of the research.

2.6 The IRB meeting minutes will record the name of the IRB member with the conflict of interest and indicate that he/she was recused and did not vote.



1.0 Purpose

The purpose of this SOP is to describe the IRB's program of continuing education for IRB members and HRPP staff.

2.1 Policy

It is the policy of the IRB to provide IRB members and HRPP staff with ongoing education concerning new regulation, new OHRP guidance documents, Association for the Accreditation of Human Research Protections Programs (AAHRPP) accreditation standards, issues in the field of research ethics, OHRP compliance citations, and other subjects of interests, which are related to human participant protection.

- 2.2 CITI certification is valid for three (3) years. When re-certification is required, IRB members and HRPP staff must complete the continuing education modules available through the CITI training program.
- 2.3 The IRB website is regularly updated and maintains links to OHRP and other sites of interest to IRB members and HRPP staff. IRB members and HRPP staff are encouraged to access these sites for current issues relating to human participant research protection.
- 2.4 IRB members and staff are provided educational items at each Board meeting. These items may be current journal articles addressing issues of human participant research; new or updated guidance issued by OHRP; or other items of interest.
- 2.5 Publication of new books on research ethics and protection of human participants are available to IRB members and HRPP staff.
- 2.6 The IRB Chair may attend conferences on human research participant protections for the purposes of continuing education.
- 2.7 Members of the HRPP are offered the opportunity, on a rotational basis, to attend regional and national conferences on human subject protections.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.006

Title: Continuing Education: IRB Members & HRPP
Staff

Section: *IRB Membership & Standard Operating
Procedures*

Date: December 5, 2017

Reviewed: August 24, 2020

- 2.8** HRPP staff members are required to obtain Certification for IRB Professionals (CIP) obtained through passing a national examination.

**1.0 Purpose**

The purpose of this SOP is to describe evaluation of the performance of IRB members.

2.1 Policy

It is the policy of the IRB to carry out evaluations of IRB members and provide feedback as necessary to individual IRB members.

2.2 IRB members are evaluated on an annual basis by the IRB Chair and Director.

2.3 Performance assessment is based upon meeting attendance records, thoroughness of reviews, participation in IRB discussions, and service on subcommittees.

2.4 IRB members are chosen by, and serve at the discretion of, the IO in consultation with the IRB Chair and Director. Members who do not adequately fulfill their responsibilities as judged by the IRB Chair may be asked to step down from IRB membership by the IO. Members missing three (3) meetings in a one-year period may be removed from the IRB. A warning notice will go out after the second (2nd) absence. IRB members may be granted an extended leave due to medical, personal, or professional reasons, then return to complete their term.

2.5 If an IRB member's performance is determined to be deficient, the IRB Chair will discuss his/her concerns with the member and seek a satisfactory resolution.

2.6 Any IRB member whose contribution to the IRB is determined to be deficient can have his/her appointment terminated by the IO upon recommendation by the IRB Chair.

2.7 If an IRB member's appointment is terminated, the IO will notify the member in writing. The IO, at his/her discretion, may notify the IRB member's supervisor or other administrative officials.

2.8 Upon request of individual IRB members, the Director and/or IRB Chair will



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.007

Title: Evaluation of IRB Members

Section: *IRB Membership & Standard Operating
Procedures*

Date: December 5, 2017

Reviewed: August 24, 2020

write letters of recommendation, which attest to the quality and value of the member's service on the IRB.

- 2.9** The IRB Chair is chosen from existing members of the IRB by the IO. The Chair should be a tenured faculty member of UMCP. The Chair is evaluated on an annual basis by the IO and the Director.
- 2.10** The appointment of the IRB staff is conducted by the IO. The selection process is overseen by the Director. The IRB staff members are annually evaluated by the Director, who in turn is evaluated by the IO or his/her designee.
- 2.11** Alternate members are chosen on the basis of availability and specialty need. They are listed on the membership roster. If serving as a substitute for a specific meeting, alternates will receive the same project material all other IRB members will receive.
- 2.12** The Director, Chair, and Institutional Official meet bi-annually to decide who has various responsibilities for the Human Research Protection process to be effective.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 2.008

Title: IRB Member Confidentiality

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: August 24, 2020

1.0 Purpose

The purpose of this SOP is to describe the requirements for IRB members to maintain the confidentiality of project reviews.

2.1 Policy

It is the policy of the IRB to maintain strict confidentiality of all reviews and other actions.

- 2.2 All IRB members will keep confidential all projects and other information pertaining to research reviewed by the IRB, which is unavailable to non-IRB members.
- 2.3 All printed IRB review material must be secured in a locked personal file cabinet or disposed of in a manner which preserves confidentiality. IRB material should not be left unsecured in the IRB meeting room. Materials are left in the room at the end of the meeting for proper disposal/shredding by IRB staff.
- 2.4 Projects without a proprietary information/confidentiality restriction may be discussed with expert internal or external consultants. In such cases, the IRB office should be notified. Confidentiality should be safeguarded by assigned consultants.
- 2.5 In the case of protocols with a proprietary information/confidentiality restriction, which require consultation with an internal or external consultant, the IRB office should be notified in advance and approval obtained from the IRB Chair. Confidentiality should be safeguarded by assigned consultants.
- 2.6 All IRB members will have a signed Confidentiality Agreement on file in the HRPP Office.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.009

Title: IRB Reviewer Assignment

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: August 24, 2020

1.0 Purpose

The purpose of this SOP is to describe IRB reviewer assignment for full board meetings and expedited review.

2.1 Policy

It is the policy of the IRB to assign reviewers who have the necessary scientific/scholarly expertise in the area of research under review.

- 2.2** A Research Compliance Analyst, in consultation as necessary with the IRB Chair and Director or IRB Manager, will assign reviewers for full board meetings.
- 2.3** At least one (1) of the assigned reviewers for the full board meeting must have the necessary scientific/scholarly expertise in the area of research under review, or the services of an expert consultant can be used.
- 2.4** The IRB Chair, voting members from the committee and a trained IRB staff person are able to review and approve projects qualifying for expedited review.
- 2.5** Each IRB member receives the following documentation, as applicable:
 - A.** The full protocol or a project summary containing the relevant information needed to determine whether the proposed research fulfilled the criteria for approval.
 - B.** Proposed consent/assent documents.
 - C.** Recruitment materials.
 - D.** The DHHS-approved protocol (when one exists).
 - E.** Sponsor's protocol/Investigator's brochure (if either exist).



If an IRB member requires additional information to complete the review, they may contact the investigator directly or may contact the IRB Office to make a request of the investigator.

Project reviewers will use the Criteria for Approval Guidance Document as a guide to completing their review.

- 2.6** For continuing review of research by a convened IRB, each IRB member receives access to the following documentation, as applicable:
- A.** Complete approved protocol, including approved consent/assent forms, recruitment materials, data collection instruments.
 - B.** Continuing Review application.
 - C.** Updated informed consent/assent form(s) if applicable.
 - D.** Any modifications made to the project (previously approved or proposed)
 - E.** Any publications that have been made as a result of the research.

In conducting continuing review of research not eligible for expedited review, all IRB members are provided and review all of the above material. At the meeting, the primary reviewer leads the IRB through the completion of the regulatory criteria for approval.

- 2.7** In conducting continuing review under expedited review, the reviewer receives access to all of the material reviewed by the reviewer(s) during the initial review. The reviewer applies the regulatory criteria for approval and generates modifications to the PI if necessary and/or provides feedback for approval.
- 2.8** For expedited review of protocol modifications, the reviewer receives access to all of the material reviewed by the reviewer(s) during the initial review and continuing reviews (if applicable). The reviewer applies the regulatory criteria for approval generates modifications to the PI if necessary and/or provides feedback for approval.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.009

Title: IRB Reviewer Assignment

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: August 24, 2020

- 2.9** For full review of project modifications/tabled project, at the meeting, the primary reviewer presents an overview of the modifications and leads the IRB through the completion of the regulatory criteria for approval. All board members receive the complete project which includes a complete history of the project along with the requested modification materials.



1.0 Purpose

The purpose of this SOP is to describe the procedures for submission of review by IRB members.

2.1 Policy

It is the policy of the IRB to encourage IRB reviewers to submit comments regarding the IRB application, the detailed protocol, the consent/assent documents, and other pertinent issues. Comments will be submitted electronically via IRBNet. Members who will not be present at the meeting may also submit their comments via IRBNet.

- 2.2 Reviews are summarized and presented at the IRB meeting.
- 2.3 Significant deficiencies and/or major points of clarification, which require revision of the IRB application, should be described fully, sequentially, and referenced to sections of the IRB application. The detailed protocol should be referenced, as necessary.
- 2.4 Significant deficiencies (i.e. errors, inadequate explanations, non-disclosure of pertinent information such as risk(s), and excessively high readability level) should be described sequentially according to the section of the consent form (i.e. elements of consent).
- 2.5 It is not necessary to comment on format or standardized elements. The IRB staff will add any necessary prescriptive changes to the review letter.
- 2.6 IRB reviewers should refrain from editorializing relative to either the application or the consent/assent document.
- 2.7 If any IRB member wishes to assist an investigator in carrying out revisions for minor improvement of language, this assistance should be accomplished via a post-IRB review personal consultation. The IRB review letter should refer to this consultation as the mechanism by which further details will be provided.
- 2.8 IRB determination letters, which reflect the decisions of the board, are developed by the IRB staff in consultation with the IRB Chair. The PI will receive the determination letter within five (5) days of the IRB Meeting.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**

Research Compliance Office
Institutional Review Board

Policy #: 2.010

Title: IRB Member Reviews and IRB Determination Letter

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 3, 2020

- 2.9** IRB determination letters must be written in a clear, explanatory, and facilitative fashion in order to assist investigators in understanding the rationale for any IRB concerns and mandated changes to the protocol and consent/assent documents.



1.0 Purpose

The purpose of this SOP is to describe IRB quorum and voting requirements.

2.1 Policy

It is the policy of the IRB to conduct full board meetings in compliance with Health and Human Services regulations at 45 CFR §46.108(b).

2.2 A full board meeting cannot be convened without the presence of a quorum. A duly constituted quorum must include: a simple majority of the voting membership. The minutes reflect what capacity each member is serving for that meeting.

A. Quorum is defined as the minimum number of IRB members that must be present at the IRB Meeting to make an action/vote valid. For example, if 14 members are on the IRB Member roster, quorum is defined as 8 voting members present at the IRB Meeting (inclusive of at least one non-scientist member).

The Research Compliance Analyst has the responsibility to monitor members present at the convened meetings and determine that meetings are convened appropriately and remain so.

2.3 When the IRB reviews any projects, amendments, unanticipated problems involving risks to participants or others, adverse events, or compliance problems related to research involving prisoners a prisoner representative must be present in accordance with 45 CFR §46.304(b) (HRPP Policy #[5.003](#)).

2.4 IRB members who abstain from voting (recorded as an abstention) are included in the quorum.

2.5 Any IRB member who has a conflict of interest will be recused in accordance with Health and Human Services regulations 45 CFR §46.107(d). IRB members with a conflict of interest are prohibited from participating in the discussion or from voting and will only provide information upon request of the IRB (HRPP Policy #[3.007](#)).



- 2.6** If attendance at a convened full board meeting falls below a quorum, the meeting will be adjourned and reconvened at the earliest possible time, but in no case, later than ten (10) business days after the adjourned meeting.
- 2.7** No motion shall pass unless a simple majority of the IRB members, which constitute a quorum, are present (in person, audio or video conference, or web with video exchange) during the discussion and vote in favor of the motion. If a member must leave the meeting temporarily (i.e. bathroom or phone call) before the vote is taken, the vote can be delayed. Voting by absentee is not permitted. If a motion fails to pass by a simple majority vote, other motions will be entertained. If no further motions are made, the project or issue under discussion shall automatically be deemed to have been tabled and shall be referred, as needed, to an IRB subcommittee for further study.
- 2.8** The general attendance at convened meetings of at least one member who represents the general perspective of participants, one member who is unaffiliated with the Institution and one member who is a non-scientist will be documented in the minutes.
- A.** The member representing the general perspective of the participants, the unaffiliated member, and non-scientific member may be represented by one person or they may be represented by two or three different persons.
- B.** It is not required that the unaffiliated member(s) are present at each meeting.
- C.** A non-scientist member must be present in order to constitute a quorum.
- 2.9** At the discretion of the IRB Chair, voting may be by written ballot, a show of hands, or voice vote. The official meeting minutes will record, without individual identification, the number of votes to approve, disapprove, table, or abstentions.
- 2.10** Whenever an issue arises during an IRB meeting, the minority opinion will be included in the minutes of the meeting. Any additional controverted issues will be included in the minutes as well.

**1.0 Purpose**

The purpose of this SOP is to describe the requirements for minutes of IRB meetings.

2.1 Policy

It is the policy of the IRB to maintain minutes of IRB meetings in accordance with Health and Human Services regulations at 45 CFR §46.115(a)(2).

- 2.2** The IRB minutes will include a) core minutes and b) detailed review letters to investigators, which are cited as addenda in the core minutes and thus are an official component of the minutes.

- 2.3** The core IRB minutes will identify the IRB members who are present, IRB alternates who are serving to replace an IRB primary member, IRB alternates who are non-voting and are present, consultants, and administrative staff who are present, and any guests in attendance at the meeting.
 - A.** Core minutes will include a record of alternate members who are serving in the place of a primary member.

 - B.** Minutes may also include justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.

- 2.4** The core IRB minutes will include 1) names of the IRB members who have a conflict of interest and are recused (absent) from the discussion and the vote, and 2) a notation indicating that a conflict of interest was the reason for the absence.

- 2.5** The core IRB minutes will include the names of IRB members who do not have a conflict of interest, but are absent from the room at the time of the vote.

- 2.6** The core IRB minutes will include vote counts for all board actions (e.g. for, against, and abstentions).



- 2.7** The core IRB minutes will include a written summary of the discussion and resolution of controverted issues. A controverted issue is clarified for the purposes of this policy as one which generated a contentious discussion among IRB members regarding a human participant protection issue. Examples include, but are not limited to:
- A.** Concerns over the acceptability of the risk-benefit relationship of the research.
 - B.** Concerns over additional protections for a vulnerable participant population and whether the project meets the requirements of Subpart C or D.
 - C.** Concerns over the investigator's qualifications.
 - D.** Justification of deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
 - E.** Concerns related to noncompliance.
- 2.8** The core IRB minutes will include a determination of when continuing review is required more often than annually, as required by the Health and Human Services regulations at 45 CFR §46.109(e). This determination will be based on factors such as: the risk level of the research, inclusion of a vulnerable population, and a history of noncompliance.
- 2.9** The core IRB minutes will include the length of time of an approval for both full board and expedited projects.
- 2.10** The core IRB minutes will include specific comments relevant to the inclusion of certain (e.g. vulnerable) populations.
- 2.11** The core IRB minutes will include an IRB determination of which projects need verification from sources other than the investigator that no material changes have



occurred since the previous IRB review. This determination will be based on a history of noncompliance as well as other factors the IRB deems appropriate.

- 2.12** In addition to the review of pending applications, meeting minutes may include information regarding expedited approvals, modifications, continuing reviews, exempt projects, and any other business appropriate for IRB meetings.
- 2.13** The IRB determination letters sent to investigators will include the following:
- A.** The basis for requiring changes in or disapproving research.
 - B.** IRB required modifications of the initial application, detailed protocol, consent/assent documents, requested clarifications, and additional information.
 - C.** IRB required modifications of amendments to the IRB application and consent/assent documents.
 - D.** IRB required actions in response to reports of unanticipated problems involving risk to the participant or others.
 - E.** Documentation of compliance with the requirements of Health and Human Services regulations at 45 CFR §46 Subparts B, C, and D as applicable, including document of determinations required by the regulations and the protocol-specific findings justifying those determinations.
 - F.** Documentation of compliance with Health and Human Services regulations at 45 CFR §46.111(b), which require additional protections for vulnerable participants, such as decisionally impaired persons, economically or socially disadvantaged persons, and terminally ill patients.
 - G.** Documentation of IRB determinations involving waiver or alteration of informed consent, in accordance with Health and Human Services regulations at 45 CFR §46.116(e)(f) including protocol-specific findings justifying those determinations (HRPP Policy #[9.006](#)).



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.012

Title: IRB Minutes

Section: *IRB Membership & Standard Operating
Procedures*

Date: December 5, 2017

Revised: September 3, 2020

- H.** Documentation of IRB determinations involving a waiver of the requirement for obtaining a signed consent form in accordance with Health and Human Services regulations at 45 CFR §46.117(c)(1)(2).
- 2.14** Copies of the core minutes are distributed to IRB members electronically through IRBNet. The core minutes are also available for review by the IO and other administrative officials as appropriate.
- 2.15** The IO and all IRB members have access to complete copies of the IRB minutes, which include the appended IRB determination letters. The letters are also kept on file in IRBNet and can be reviewed as requested.
- 2.16** The complete IRB minutes will be provided to OHRP, auditing groups, and the courts in accordance with all applicable federal, state and institutional requirements.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 2.013

Title: HRPP Policy Review and Approval

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 3, 2020

1.0 Purpose

The purpose of this SOP is to describe the review and approval process for HRPP policies

2.1 Policy

It is the policy of the IRB to continually, and at least annually assess the adequacy of existent policies and the need for new policies as the field of research ethics and human participant protection evolves. At least annually the Director will send an email communication to IRB members asking them to review existing HRPP policies and procedures and assess the adequacy of policies and the need for new policies.

- 2.2 Proposed HRPP policies, which impact significantly the IRB review system, investigators, and the Institution will be reviewed and approved by the IRB with the Chair acting as designated signatory, the Director, the IO, and in some cases the President. HRPP internal administrative policies will be given to the IRB for their information, but do not require formal approval.
- 2.3 When a draft policy is scheduled for review at the IRB meeting, all members of the IRB will be given a copy of the draft policy approximately one week in advance of the meeting.
- 2.4 All IRB members will be invited to attend the meeting at which the policy will be reviewed.
- 2.5 All IRB members have the right to cast their vote (for, against, abstain) either in person at the IRB meeting or via email. IRB members may provide written statements in support of their vote or ask other IRB members to express their opinions at the meeting.
- 2.6 In instances where approval of a policy is necessary before the next regularly scheduled meeting, voting procedure by email alone will be allowed for consideration of a policy.
- 2.7 In order for a policy to be approved or disapproved, two-thirds of the entire IRB membership must vote in favor, either in person or by email, for the motion to carry.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.013

Title: HRPP Policy Review and Approval

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 3, 2020

- 2.8** If the motion to approve a policy fails to pass, the draft policy may be referred to the IRB Chair or an IRB subcommittee for further discussion and revisions before reconsideration.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.014

Title: IRB Records

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 3, 2020

1.0 Purpose

The purpose of this SOP is to describe the maintenance and composition of IRB records.

2.1 Policy

It is the policy of the IRB that records will be maintained in full accordance with Health and Human Services regulations at 45 CFR §46.

2.2 Under Health and Human Services regulations at 45 CFR §46.115, the IRB will maintain documentation of all IRB activities.

2.3 Where appropriate, the IRB office will maintain all records, reports, and other required documents as specified by federal regulations and UMCP policies on records retention. The following documentation will be maintained for a minimum of three years following the closure of the IRB approved project:

- A.** Copies of all research protocols reviewed.
- B.** Scientific evaluations, if any, which accompany the protocols.
- C.** Progress reports submitted by the research investigators.
- D.** Reports of injuries to participants.
- E.** Reports of unanticipated problems involving risk to participants (including adverse event reports) and documentation of IRB review of these reports.
- F.** Minutes of IRB meetings.
- G.** Records of continuing review activities.
- H.** Copies of all correspondence between the IRB, the IRB office, and the research investigator.
- I.** List of IRB members and alternates.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.014

Title: IRB Records

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 3, 2020

- J. Consent documents.
- K. Statements of significant new findings provided to participants.
- L. Records pertaining to research, which is conducted, must be stored securely in the IRB office, and must be retained for at least three (3) years after completion of the research. Paper records will be stored at the State Records Facility for at least three (3) years after project closure. Electronic records will be stored in IRBNet.

2.4 The IRB project files (paper and electronic) will include:

- A. IRB application.
- B. Detailed protocol (if available).
- C. Federal grant applications (as appropriate).
- D. Approved informed consent/assent documents (as appropriate).
- E. Initial IRB determination letter to the PI, including citations of appropriate federal regulations utilized during IRB review of research involving: pregnant women (45 CFR §46 Subpart B), prisoners (45 CFR §46 Subpart C) and/or children (45 CFR §46 Subpart D).
- F. PI response to IRB determination letter.
- G. Further correspondence regarding IRB review of the application.
- H. Final IRB approval letter. The letter must include documentation of approvals under Health and Human Services regulations for exempt status [45 CFR §46.101(b)], and expedited status [45 CFR §46.110].



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.014

Title: IRB Records

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 3, 2020

- I. For protocols granted exempt status, the file will include documentation of the exemption. Documentation of verified exemptions consists of a reviewer's citation of a specific exempt category and written concurrence that the activity described in the investigator's request satisfies the conditions of the cited exempt category. The exempt determination is reported at the next convened IRB meeting and documented in the minutes (HRPP Policy #[4.001](#)).
- J. IRB approved recruitment materials and copies of the IRB approved project materials.
- K. All requests for changes and the correspondence pertaining to the request. Copies of the modified IRB approved consent/assent forms and/or protocols associated with the request.
- L. All continuing reviews and the correspondence pertaining to the request. Copies of the consent documents approved in conjunction with the continuing review.
 1. IRB records for initial and continuing review by the expedited procedure must include: the specific permissible category, a description of action taken by the reviewer, the approval period and any determinations required by the regulations including protocol-specific findings supporting those determinations.
- M. IRB records must also document any determinations required by the regulations and protocol-specific findings supporting those determinations, including:
 1. Waiver or alteration of the consent process.
 2. Research involving pregnant women, fetuses, and neonates.
 3. Research involving prisoners.
 4. Research involving children.
- N. All interim progress reports.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.014

Title: IRB Records

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 3, 2020

- O.** Reports of unanticipated problems (internal adverse events, internal fatal adverse events, external adverse events, and unanticipated problems involving risk to the participant or others) and the correspondence pertaining to the reports. (Copies of supporting documentation and consent documents will be attached to the report).
 - P.** Incidents of noncompliance, including documentation of investigation, correspondence, and reports to institutional officials and OHRP, where appropriate.
 - Q.** Results from correspondence regarding the findings.
 - R.** IRB records for initial and continuing review by expedited review and approval:
 - 1.** The specific permissible category.
 - 2.** Description of action taken by the reviewer.
 - 3.** Any determinations required by the regulations, along with project specific findings justifying those determinations.
- 2.5** The project file is maintained electronically on IRBNet.
- 2.6** Existing paper copies of IRB projects that remain open after the implementation of IRBNet will be maintained in the HRPP office until the project is completed or terminated. Once completed or terminated, these paper files will be archived and set to the State Records Archive for at least three (3) years. After which, they will be destroyed.
- 2.7** The IRB uses IRBNet as its electronic project submission system and project archive (implemented February 15, 2012). IRBNet maintains all relevant project and review information including the following:
- A.** IRB project number.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 2.014

Title: IRB Records

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 3, 2020

- B. Project title.
- C. Review category and review path (exempt, expedited, or full board).
- D. Date project was received, date of full board meeting(s), approval, closure, continuing review, date for reminders, data of requested modifications.
- E. Status of the project (approved, disapproved, pending review, tabled, terminated, closed, withdrawn).
- F. PI's name and contact information.
- G. Special considerations (videotaping, audiotaping, chemical materials, radioactive materials, photography, etc.)
- H. Funding source.
- I. Investigator type (faculty, graduate student, advisor, undergraduate, etc.)
- J. Project type (research, class project, program evaluation, etc.)
- K. Number of participants to be enrolled.
- L. Types of participants (adults, minors, prisoners, pregnant women, other vulnerable populations).
- M. Waivers (HIPAA, consent).

2.8 IRBNet maintains investigator training records for each submitted project.



1.1 Purpose

The purpose of this SOP is to describe activities requiring IRB approval.

- 1.2 Systematic Investigation:** is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis in order to answer a question.

Therefore, you have research when the prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis in order to answer a question is designed to develop or contribute to generalizable knowledge.

2.1 Definitions

- 2.2 Research** is defined by DHHS regulations at 45 CFR §46.102(l) as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

Activities that meet this definition may be funded or unfunded or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.

The **Belmont Report** provides further clarification of “research” as follows: “... the term ‘research’ designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).”

Research is defined by FDA regulations as any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under Section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these Sections of the act, but the results of , which are intended to be submitted later to, or held for inspection by the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include, experiments



**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.001

Title: Investigational Activities Requiring IRB Review
and Approval

Section: *IRB Membership & Standard Operating
Procedures*

Date: December 5, 2017

Revised: September 3, 2020

that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies. An experiment, as defined in 21 CFR 312, includes any use of a drug other than the use of a marketed (approved) drug in the course of medical practice.

- 2.3 Human Subject** is defined by DHHS regulations at 45 CFR §46.102(e)(1) as, “a living individual about whom an investigator (whether professional or student) conducting research, i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or ii) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or iii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. It also includes interaction with identifiable, private information.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

In this set of policies, the word “participant” is substituted for the word “subject”.

Human subject as defined by FDA regulations is an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. In the case of a medical device, a human subject/participant also means a human on whose specimen an investigational device is used.

Human Participant Research for the purposes of this policy is defined as an activity that meets the definitions of “research” and involves “human subjects” as defined either by HHS regulations or by FDA regulations.



**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.001

Title: Investigational Activities Requiring IRB Review and Approval

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 3, 2020

Intervention includes both physical procedures by which data are gathered (e.g., drawing blood) and manipulations of the participant or the participant's environment that are performed for research purposes.

- 2.4 Interaction** includes communication or interpersonal contact between investigator and participant. It also includes interaction with identifiable, private information.
- 2.5 Private Information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual, and which the individual can reasonably expect will not be made public (e.g., medical record information).
- 2.6 Individually Identifiable Information** is information where the identity of the participant is or may readily be ascertained by the investigator or associated with the information.
- 2.7 Systematic Investigation**, for the purposes of this policy, is an activity that involves a prospective research plan that incorporates data collection, either quantitative or qualitative, and data analysis in order to answer a research question.
- 2.8** Investigations designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions (i.e. knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

3.1 Policy

IRB approval is required for **all** research involving human participants as defined above, which is conducted by faculty, students, staff, or others under the jurisdiction of the IRB, (i.e. research performed on the premises of UMCP, as well as research involving human participants conducted elsewhere by investigators as part of their institutional responsibilities, unless the investigation is conducted under a cooperative research agreement.)

In reviewing research involving human participants, the IRB will apply 45 CFR §46 in accordance with HRPP Policy #[1.002](#). The IRB does not review activities which do not meet the definitions of research involving human participants under 2.1 and 2.2 above.

3.2 Classification of Human Participant Research

A. Social Science, Behavior and Education Research



**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.001

Title: Investigational Activities Requiring IRB Review and Approval

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 3, 2020

Social science and behavioral research includes all research performed with intent to develop generalizable knowledge (i.e. test a hypothesis and draw conclusions) about behaviors, attitudes and interactions among and between individuals, groups, and cultures. Generally, this category of research has no intent of producing a diagnostic, preventative, or therapeutic benefit to the participant who is not seeking nor expecting a health benefit from the research. There may, or may not, be any prospect of direct participant benefit associated with this category of research.

Types of research involving human participants that may fall under the social science and behavioral research category include, for example:

1. Qualitative social science research
2. Ethnographic research
3. Observational research
4. Survey research
5. Education research
6. Criminal justice research
7. Other (for example, an engineering project might research how individuals respond to certain engineering techniques)

B. Biomedical Research

Biomedical research at UMCP, generally, but not exclusively, refers to clinical/patient-oriented investigations, biomedical engineering research, and exercise science and nutrition studies research.

3.3 Not Human Participant Research

A. Oral History

Most oral history interviewing projects are not subject to the requirements of the Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46, subpart A, and can be excluded from institutional review board (IRB) oversight because they do not involve research as defined by the HHS regulations. HHS regulations at 45 CFR 46.102(d) define research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” The Oral History Association defines oral history as “a method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life.”



**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.001

Title: Investigational Activities Requiring IRB Review and Approval

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 3, 2020

It is primarily on the grounds that oral history interviews, in general, are not designed to contribute to “generalizable knowledge” that they are not subject to the requirements of the HHS regulations at 45 CFR §46 and, therefore, can be excluded from IRB review.

B. Quality Improvement

In general, quality improvement projects are not considered research unless there is a clear intent to use the data derived from the project to contribute to generalizable knowledge.

C. Student Projects

When there is clear intent to conduct a systematic investigation designed to develop or contribute to generalizable knowledge, then student projects are considered research. This might be indicated, for example, by publication in a peer review journal and/or presentation at a national or regional meeting. However, a student project that is presented, for example, as a poster or a seminar *within the academic confines of the Institution only*, and is not intended to contribute to generalizable knowledge, generally is not considered research. In this case, the student’s supervisor and/or department are responsible to exert appropriate oversight of the project and to consult with the HRPP office as needed.

3.4 Human Participant Research Determination

Any individual who is unsure if a proposed activity constitutes “research involving human participants” should complete a Human Participants Research Determination form and submit through IRBNet. HRPP staff and/or the IRB Chair will review this form and determine whether a given project is subject to 45CFR§46 and any other requirements dictated by a federal sponsor. If not, the IRB Office will provide an official memo to the PI if the project does not qualify as human subject research. If the project does qualify as human subject research, the PI will be instructed to complete and submit the necessary IRB application documents.

When there is any question concerning whether or not an investigator will be engaged in research, HRPP staff and/or the IRB Chair will consult with OHRP.

Decisions about whether an activity represents human participant research are made promptly and conveyed to the individual seeking an opinion. All decisions will be



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.001

Title: Investigational Activities Requiring IRB Review
and Approval

Section: *IRB Membership & Standard Operating
Procedures*

Date: December 5, 2017

Revised: September 3, 2020

explained fully in order to ensure the Institution's faculty, staff, and students understand the criteria used in making the determination.

3.5 Review Path

The project review path (full board, expedited, exempt) will be determined by HRPP staff or in consultation with the IRB Chair. This includes reporting of findings that could affect the safety of participants or influence the conduct of the study. The OHRP Human Subject Regulations Decision Charts (September 24, 2004) will be used as necessary in determining the review path:

<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

3.6 Sponsored Research

- A.** The University agrees to follow the research protocol, applicable state and federal law, and UMCP's ethical standards.
- B.** The sponsor agrees to follow UMCP's policies and procedures regarding the dissemination and publication of findings from sponsored research.
- C.** When participant safety could be directly affected by study results after the study has ended, UMCP will have a written agreement with the sponsor that the researcher or UMCP will be notified of the results in order to consider informing participants.



**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.002

Title: Ethical Principles Governing Research under Jurisdiction of the IRB

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 14, 2020

1.0 Purpose

The purpose of this SOP is to describe the ethical principles, which govern research under the jurisdiction of the IRB.

2.1 Policy

It is the policy of the IRB that all research which is reviewed and approved by the Board and conducted under its' jurisdiction will generally conform to the following guidance documents: 1) [The Nuremberg Code](#) and 2) [The Belmont Report](#). Health and Human Services regulations 45 CFR §46 reflect the basic ethical principles for the conduct of human participant research found in these documents.

All researchers, participating personnel, and IRB members are charged with upholding the ethical principles contained in the aforementioned guidance documents as they apply to the research project in question. The IRB project and consent document review form and the process of IRB review is designed to help IRB members and investigators ensure that research reflects the highest possible ethical standards (HRPP Policy [3.004](#)).

2.2 The Nuremberg Code

The Nuremberg Code contains 10 basic ethical principles, which are presented in abbreviated form below:

- A. Obtain voluntary consent of the participant.
- B. Design the study to yield results for the good of society, otherwise unobtainable through other means.
- C. Base studies involving humans on animal experiments.
- D. Avoid physical and mental suffering and injury to the participant or others.
- E. Do not conduct the study if death or disabling injury is an expected result.
- F. The degree of risk should never exceed the humanitarian importance of the problem to be solved by the research.
- G. Protect the participant from injury, disability, or death.
- H. Be scientifically qualified to conduct the study.
- I. Allow the participant to voluntarily withdraw at anytime.
- J. Be prepared to stop the study when continuation is likely to result in injury, disability, or death to the participant.

2.3 The Belmont Report

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research released the "Belmont Report: Ethical



**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.002

Title: Ethical Principals Governing Research under
Jurisdiction of the IRB

Section: *IRB Membership & Standard Operating
Procedures*

Date: December 5, 2017

Reviewed: September 14, 2020

Principals and Guidelines for the Protection of Human Subjects of Research.” The three basic ethical principles described in the Belmont Report are:

A. Respect for Persons

The ethical principal of respect for persons has two components: acceptance of individual autonomy and protection of those with diminished autonomy.

Autonomous individuals demonstrate the ability to make informed choices and act on those choices. These choices must be acknowledged and accepted by others as a demonstration of respect, as long as those choices are not harmful to others. Conversely, it must also be recognized that some individuals may be incapable of making informed choices and require special protection. The principle of respect for persons in the research context is demonstrated through the process of informed consent, including the process of assent and proxy consent for potential participants requiring special protections.

B. Beneficence

The principle of beneficence is defined in two ways: (1) do no harm, and (2) maximize the potential benefits and minimize all potential harms (e.g. risks) related to research participation. While there is an imperative that no harm comes to the participant, it should be recognized that there is potential for harm due to unknown factors associated with the research. To minimize this risk, the potential benefits to the participant and society must be determined and maximized.

C. Justice

The principle of justice implies a sense of “fairness.” Justice occurs when the burdens and benefits are equally carried by all. To achieve justice in the research context, recruitment of potential participants must occur without discrimination, bias, or undue influence in order to distribute the burdens and benefits of research equitably for individual and society. Inequities must be justified.



1.0 Purpose

The purpose of this SOP is to describe IRB deadlines, submission materials, and the IRB pre-review process.

2.0 IRB Deadlines

Application forms can be found in IRBNet under the IRB Document Library or Forms and Templates. Submission deadlines and IRB meeting dates can be found on the HRPP website: <https://research.umd.edu/irbprocess>. Full board reviews must be submitted by the published submission deadline to be considered for placement on the next IRB meeting agenda. Incomplete submissions may result in the delay of IRB review.

3.1 Submission of Initial Application Materials

A copy of each of the following (as applicable) must be submitted through IRBNet.

3.2 IRB Application Part 1

This is an electronic document that must be completed for each Initial Application. Once complete, a PDF is generated and automatically attached to the project.

3.3 IRB Application Part 2

This is a Word document with eleven (11) sections that must be completed for each Initial Application. The Initial Application Completion Guide should be consulted in order to complete this document appropriately.

3.4 Informed Consent and Assent Form(s)

The consent and assent process and documents must be appropriate for the proposed study population (e.g. adult, parental, minor, etc).

[DHHS Consent Form Guidance](#)

3.5 Participant Recruitment Material(s)

Copies of all advertisements, flyers, email, transcripts of broadcast materials and other recruitment material must be provided for IRB review.

3.6 Description of Performance Site(s) for Non-Institutional Sites

Performance sites are defined as (1) sites where Institution investigators or staff interact with participants, collect data, or solicit consent, or (2) sites over which the IRB has responsibility. Performance sites do not include other sites participating in a multi-center study which have an IRB. All performance sites must be identified.

**3.7 Other Relevant Materials**

- A.** Copies of all research measures (surveys, questionnaires, interview questions, focus group questions, etc.) and other relevant materials must be submitted for IRB review.
- B.** Where applicable, a copy of the detailed protocol and a copy of the grant narrative pertaining to human participant research activities.

4.1 IRB Pre-review

As a new project is created in IRBNet, it will be assigned a seven-digit project number along with the number of the package after a dash (the first is -1). Subsequent packages under this project will proceed sequentially (-2, -3, etc.).

All projects submitted for IRB review are screened by IRB staff. Specifically, the project application will be screened to determine:

- 4.2** All required documents have been submitted and are complete.
- 4.3** All personnel listed on the application are currently CITI Certified(required human subjects training). See HRPP Policy#[3.009](#).
- 4.4** The PI and listed personnel will receive email sent through IRBNet to correct errors, provide missing documents, or provide additional information as necessary.

The Analyst(s) will determine, with the advice of the IRB Chair/Vice-Chair, whether a project qualifies for Expedited or Full Board review. IRB Committee Members will be assigned as reviewers for projects requiring full committee review.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.004

Title: Criteria for IRB Approval of Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 14, 2020

1.0 Purpose

The purpose of this SOP is to describe the criteria required for IRB approval of Expedited or Full Board reviewed research projects.

2.1 Policy

It is the policy of the IRB that all Expedited and Full Board research projects will undergo a rigorous review which will allow a determination that the project meets: 1) the criteria specified in Health and Human Services regulations at 45 CFR §46.111 and 2) IRB HRPP policies and procedures. 45 CFR §46.111 criteria are listed as follows and are the reference guide for all IRB review.

2.2 In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

- A.** Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- B.** Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- C.** Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.



- D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.117.
- E. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
- F. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- G. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- H. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

- 2.3** The IRB approval criteria are described in the Initial Application Part 2 – Completion Instructions document. Guidance for appropriate responses in each section of Initial Application Part 2 is provided.

3.1 Criteria for IRB Approval

3.2 Purpose of the Study

The IRB will determine if the background and literature citations support the stated purpose of the study. See HRPP Policy [#3.006](#).

Characteristics of the Participant Population:

The IRB will examine the characteristics of the proposed participant sample to determine if the eligibility criteria is appropriate with respect to the nature and goals of the research and the selection of participants is equitable without bias or discrimination.

3.3 Purpose of the Study

Factors to be considered: the number of participants requested, age range, sex, race/ethnicity, health status, etc. Any proposed exclusion criteria must be



scientifically justified by the investigator. In particular, the following will be examined during review:

A. Accrual

The IRB must be assured that the number of participants consented to this project is sufficient for the purpose of this study and adequate justification is provided.

B. Gender

The IRB must be assured that the proposed distribution is suitable for the purpose of the study and appropriate justification for exclusion or inclusion of males or females is provided. Women of childbearing potential and pregnant women should not be excluded from participation unless adequate justification is provided.

C. Age Range

Appropriate justification must be provided for the proposed age range as well as for the inclusion or exclusion of particular age groups. For example, minors, elderly, etc.

D. Race and Ethnicity

The proposed distribution of participants by race/ethnicity must be suitable for the purpose of the study. Appropriate justification for the inclusion or exclusion of particular persons or groups must be provided.

E. Vulnerable Participants

The IRB will determine if the research is approvable for inclusion of vulnerable populations under DHHS regulations at 45 CFR §46, Subpart C [Prisoners – HRPP Policy [5.003](#)] and Subpart D [Children - HRPP Policy [5.004](#)]. The IRB will determine if special protections are required for decisionally-impaired persons [HRPP Policy [5.005](#)] as well as other potentially vulnerable populations.

F. Eligibility Criteria

The IRB will determine if the presented Inclusion and Exclusion Criteria are



appropriate for the purpose of this project. The purpose of Exclusion Criteria is to minimize any potential risk to participants.

3.4 Methods and Procedures

The IRB will review the experimental design in order to be assured that potential risks to participants are minimized and the potential benefits are maximized by utilization of procedures consistent with sound research design and which do not unnecessarily expose participants to risk [HRPP Policy – [3.006](#)]. The IRB must determine if the interventions and follow-up activities are appropriate for the stated purpose of the research and, whenever appropriate, procedures are used which will already be performed on the participants for diagnostic or treatment purposes. Interventions and procedures considered standard of care must be clearly identified.

The IRB accepts the need for certain types of behavioral and social science projects to employ strategies that include either deception and/or the withholding of information. Employment of such strategies must, however, be adequately justified in the IRB Application. In general, deception is not acceptable, if, in the judgment of the IRB, the participant would have declined to participate had they been informed of the true purpose of the research. Studies that use deception and/or the withholding of information as part of their experimental design must meet all requirements of 45 CFR§46.116(f), described below, and include a post-study debriefing.

In the event a project employs the use of deception, the investigator must:

- A. Provide a justification for the deception;
- B. Describe the manner of deception and/or how deception will take place
- C. Note whether the deception results in any increased risk to participants; and
- D. Describe how any additional risks would be minimized (where appropriate)

3.5 Data Storage and Confidentiality

- A. The IRB will review the methods to be used to protect confidentiality and will ensure that appropriate protections are in place in consideration of the nature



of the research, the vulnerability of the participant population, and the risk associated with a breach of confidentiality.

- B.** If research data with participant identifiers will be made available to persons other than the listed investigators, sponsor, or federal agency, the IRB will review the justification for sharing this data and determine acceptability in accordance with all applicable regulations, including the HIPAA Privacy Rule [HRPP Policies: [10.001](#), [10.002](#)].
- C.** If the research involves the collection of sensitive information where a breach of confidentiality would constitute a serious risk, the IRB will consider the need for a Certificate of Confidentiality

[HRPP Policy: [3.011](#)]. The IRB may also waive documentation of informed consent in accordance with 45 CFR §46.117(c).

3.6 Risk Benefit Assessment

A. Potential Risks

Both immediate and latent (delayed) risks of any procedure involving human participants will be reviewed by the IRB to ensure that risks to participants are identified and minimized. The estimated probability, severity, average duration, and reversibility of any potential harm will be considered according to available empirical data. Furthermore, since certain populations of vulnerable participants may be at greater risk than others, the IRB will take into consideration the potential risk characterization of the participant and ensure that appropriate additional protections are in place.

B. Risk Classification

Risk is classified as: 1) minimal, or 2) greater than minimal. The IRB will review carefully the risk classification of the research, as it will determine the type of IRB review and interim review requirements.

Minimal Risk: "The probability (of occurrence) and magnitude (seriousness) of harm or discomfort (e.g., physical, psychological, social) associated with the research are not greater than those ordinarily encountered in daily life (of



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.004

Title: Criteria for IRB Approval of Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 14, 2020

healthy persons in the general population) or during the performance of routine physical or psychological examinations or tests.”

A uniform standard of minimal risk based upon the daily life of a normal, average, healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests he/she would be expected to encounter will normally be used for research involving adults. However, under certain circumstances, application of the minimal risk classification will be based upon a consideration of the risks inherent in each participant’s life thereby resulting in a relative standard of minimal risk which is more stringent. Factors such as age, repetitive procedures, and vulnerability will be considered in determining if a study qualifies as minimal risk.

When research involves children, a uniform standard of minimal risk also will be used, which is based upon the daily life a normal, average, healthy child living in a safe environment or the performance of routine psychological and medical examinations he/she would be expected to encounter as part of a standard well-child examinations.

- C. Minimization of Risk:** The IRB will review data and safety monitoring that must fit the design, nature, and risk profile of the research. In some cases, the research will require a data safety monitoring plan [HRPP Policy #[3.010](#)]. The IRB will determine whether or not a research project requires review more often than annually [HRPP Policy #[3.010](#)] and will establish an appropriate reporting and/or monitoring procedures that may include observation of the consent process, observation of on- going research, or review of research records [HRPP Policy #[7.001](#)].

The IRB also will determine whether a research project requires verification from sources other than the investigators that no material changes have occurred since the previous IRB review [HRPP Policy #[3.010](#)].



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.004

Title: Criteria for IRB Approval of Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 14, 2020

- D. Potential Benefits:** The IRB will review the anticipated benefits to both the participant and to society. In addition, the IRB will consider whether the benefits are maximized to the greatest extent possible through proper protocol design. Financial or other forms of compensation are not considered a benefit to be derived from research participation. Although the participant may consider financial compensation a desirable outcome, this fact will not be used in the risk-benefit analysis.
- E. Alternatives to Participation:** The IRB will review the alternatives outside of the research context that are available and may be of reasonable benefit to the participant.
- F. Risk – Benefit Analysis:** The IRB will examine the relationship of the risks to the benefits identified in the application. The following is a series of principles, which the IRB will take into consideration:
1. In research involving the study of the efficacy and safety of a therapeutic or diagnostic method, where there is the potential for participants to receive a direct health benefit (e.g., clinical research), the risk- benefit relationship of the research must be at least as favorable to the participant as that presented by alternate standard therapies available to the participant in the non-research context.
 2. In research involving a combination of a standard therapy (used solely for the benefit of the participant and not part of the research protocol) with specified research procedures, the anticipated benefits of the therapy must not be used to justify exposing participant to the risks associated with the research procedures. Conversely, only the risks associated with the research procedures should be used in determining acceptability of the risk-benefit relationship.
 3. In research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the subject (e.g., behavioral research and non-clinical biomedical research), the potential risk to



Policy #: 3.004

Title: Criteria for IRB Approval of Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 14, 2020

the participant must be outweighed or balanced by the potential benefit to the participant and/or by the potential benefit to society.

- 3.7 Participant Financial Obligations:** The IRB will review the financial obligations of the participant relative to participating in the study. The IRB application should clearly identify who will be financially responsible for research related interventions or procedures, as well as other potential costs of participation (e.g., travel, child care, food).
- 3.8 Compensation for Participation:** The IRB will review the amount of compensation for participation (monetary, as well as other forms) in order to ensure that it is not coercive and is fair [HRPP Policy #[3.015](#)].
- 3.9 Conflict of Interest:** The IRB will review potential conflict of interest of the principal investigators, which has been reviewed by the [Conflict of Interest in Research Committee \(COIRC\)](#) [HRPP Policy #[3.007](#)]. This review will be based upon the Board's charge to ensure protection of the rights and welfare of human participants.

This charge includes authority to:

Ensure disclosure in the consent document of any financial interests of the investigator, which are judged by the IRB to be material to the participant's decision whether or not to participate in research.

Ensure there is an appropriate plan for monitoring of the research, which may involve observation of the consent process, auditing of records, and interim reporting of research results to the IRB.

Require informed consent be obtained by a qualified individual other than the principal investigator. If the IRB finds that the conflict of interest management plan requires additional measures, the Board will alter the management plan in accordance with its charge and forward the revised plan to the Conflict of Interest in Research Officer.



Policy #: 3.004

Title: Criteria for IRB Approval of Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 14, 2020

3.10 Participant Identification and Recruitment: The IRB will review the method of prospective participant identification and recruitment in order to be assured it is ethically and legally acceptable [HRPP Policy #[3.016](#)]. Advertisements (e.g., newspaper ads, fliers, radio ads, etc.) used to recruit participants are considered an extension of the recruitment and informed consent processes, and therefore, must be reviewed by the IRB.

3.11 Informed Consent: The IRB will review both the consent form and the process of informed consent as described in the IRB application to ensure that consent will be sought only under appropriate circumstances, which allow the prospective participant to engage in thoughtful decision making.

Specifically, the IRB will determine the following:

The process of consent/assent is appropriate in consideration of the nature of the research, risks of the research, and characteristics of the participant population [HRPP Policy #[9.002](#)].

All required consent/assent document(s) utilize the appropriate IRB-approved templates [<https://research.umd.edu/irbforms>].

The informed consent form(s) contain the elements of informed consent required by Health and Human Services regulations [HRPP Policy #[9.002](#)].

The assent form(s) contain the IRB-required elements of assent [HRPP Policies #[9.002](#) and [9.004](#)].

The documentation of informed consent conforms to HRPP Policy #[9.002](#).

3.12 Investigator Qualifications: The IRB will review the PI's qualifications and must be assured:

The investigator has the appropriate qualifications and licensure (if any) to carry out the procedures involving human participants with an acceptable degree of risk. The investigator and anyone on the research team who will interact with human participants must complete the required CITI human participant research training.



The investigator has adequate facilities and equipment to conduct the research with an acceptable degree of risk.

The principal investigator must be affiliated with UMCP. For student projects, the student may act as the principal investigator; however, the faculty advisor must be listed on the project and sign the application.

3.13 Scientific and Scholarly Merit and Resource Review: The IRB must ensure that the research has undergone appropriate scientific and scholarly merit and resource review [HRPP Policy #[3.006](#)]. Prior to submission to the IRB, this is conducted by the Departmental IRB Liaison. After submission to the IRB, this is conducted by the IRB Chair or an IRB Member(s) with appropriate expertise.

4.0 If the Institution is the lead site for a multi-institutional protocol, and data are collected and analyzed at UMCP, or adverse events or serious problems tracked at UMCP, then a copy of the approval from the IRB of all reporting sites must be provided. If additional sites are added after approval of this application, then letters of IRB approval must be submitted as they become available.

Letters of agreement may be requested from study sites not associated with the Institution (such as schools, nursing homes, and prisons), stating that the site administrator is aware of the study and will allow the Institutional PI and study personnel to utilize their site to conduct the study.

5.0 IRB Reviewer Guidance: All IRB Members have access to a guidance document that outlines the Criteria for Approval in order to complete their reviews.

6.0 Office of Research Administration (ORA): All proposals for funding must be submitted to the [Office of Research Administration](#). If human participants are involved, ORA will inform the PI to contact the IRB Office. It is the responsibility of the PI to secure IRB Approval.

7.0 Additional Administrative Review: Human research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. Those officials cannot, however, approve any research project unless it is first approved by the IRB. When a study is considered controversial, particularly from a community-based standpoint, the IRB Chair will forward a copy of the protocol to the IO (or designee) and the PI will be so notified.



UNIVERSITY OF MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.005

Title: Initial IRB Review Categories

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 16, 2020

1.0 Purpose

The purpose of this SOP is to describe the IRB initial review categories.

2.1 Policy

It is the policy of the IRB that research must be appropriately classified as exempt, expedited, or full board review in accordance with Health and Human Services regulations at 45 CFR §46.

2.2 Exempt Review

If a submitted proposal qualifies for exempt status in accordance with Health and Human Services regulations at 45 CFR §46.104 (1-8), the proposal will be reviewed using the exempt review procedure once the proposal is assigned into one of the eight exempt categories (HRPP Policy [#4.001](#)).

2.3 Expedited Review

If a project or transaction involves no more than minimal risk activities or changes that qualify for expedited review status in accordance with 45 CFR §46.110, the project will be reviewed using an expedited review procedure (HRPP Policy [#4.002](#)).

After the review takes place, the investigator will be notified of the IRB's decision concerning the project. Reviewed proposals will be assigned to one of three categories:

A. Approval/Marked Exempt

The project is approved or marked exempt. The investigator may begin the study.

B. Approval with Modifications

The project is approved contingent upon IRB Chair/expedited reviewer or, unless otherwise specified, Research Compliance Analyst acceptance of specific modifications and/or clarifications.



The investigator will be notified, in writing, as to the nature of the required modifications and/or clarifications. As soon as the investigator complies in writing with all requirements, the project will be approved and the investigator may begin the study.

C. Full Board Review

The IRB Chair(s), IRB Manager, or Director determines the project or transaction should be reviewed by the full IRB. This decision may be based on the level of risk present, non-compliance, etc.

2.4 Full Board Review

Projects that do not qualify for exempt or expedited review will be assigned to the next available IRB Meeting.

After the IRB meeting, the investigator will be notified in writing of the IRB's decision concerning the proposal. In accordance with the IRB's decision, the IRB letter will specifically detail items requiring clarification, modification, or justification. The PI will be requested to respond to IRB concerns. The IRB minutes will reflect the IRB determination. Reviewed proposals will be assigned to one of five (5) categories:

A. Approval

No modifications or clarifications are required and the investigator may begin the study.

B. Approval with Specific Changes

This category is restricted to modifications/clarifications that are specific and prescriptive. The investigator will be notified in writing as to the nature of the required modifications and/or clarifications. When the investigator complies, in writing, with all requirements as determined by the IRB Chair or HRPP designee, approval will be granted and the investigator may begin the study. Approval is contingent upon IRB Chair or HRPP designee acceptance of specific modifications/clarifications



C. Tabled

This category is restricted to applications where the IRB requires a significant amount of additional information and/or has a serious concern. The investigator will be notified in writing of the IRB's decision concerning the project. The IRB Chair and/or a member of the Board may be assigned to discuss the proposal with the investigator.

When the investigators submit the required materials for re-review, the tabled protocol will be reviewed at the next IRB meeting in adherence with published submission deadlines for full board meetings. Whenever possible, the two IRB reviewers who performed the initial review will be assigned to re-review the protocol. When that is not possible, IRB reviewers are encouraged to consult, as necessary, with previous reviewers to resolve any problems or concerns, which may still exist.

D. Disapproved

This category is restricted to applications which have very serious design flaws and/or participants will be placed at undue risk. When necessary, the IRB will seek consultation from recognized experts in the field, other IRBs, OHRP, and the National Science Foundation Office of the Inspector General (OIG). Every attempt will be made to resolve the identified problem(s). The IRB, however, retains final authority over whether a project will be approved.

The investigator will be notified in writing of the IRB's decision concerning the project. The IRB Chair and/or a member of the Board may be assigned to discuss the proposal with the investigator. The investigator may submit a new application after he has taken the board's comments under consideration and consulted with an IRB-designated mentor.

E. Decline to Complete Review

This category is restricted to applications which are significantly deficient in information or content when received by the IRB Office. Consequently, adequate review of the protocol could not take place. The application will be returned to the PI with instructions to review and revise the application in



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.005

Title: Initial IRB Review Categories
Section: IRB
Membership & Standard Operating Procedures

Date: December 5, 2017

Revised: September 16, 2020

consideration of application instructions and guidelines and resubmit the application to the IRB when ready.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.006

Title: Scientific and Scholarly Merit Review of Projects

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

1.0 Purpose

The purpose of this SOP is to describe the requirements for scientific and scholarly merit review of all research proposals submitted to the IRB for review.

2.1 Policy

It is the policy of the IRB that all research proposals must undergo a scientific or scholarly merit and resource review per Health and Human Services regulations at 45 CFR §46.111(a)(1)(i) and 45 CFR §46.115(a)(1).

Prior to submission to the IRB, this is conducted by the Departmental IRB Liaison. After submission to the IRB, this is conducted by the IRB Chair or an IRB Member(s) with appropriate expertise.

- 2.2** The IRB, utilizing member expertise and/or consultants, will evaluate the scientific and scholarly validity of a proposed study. The IRB has broad-based disciplinary expertise, which allows a judgment to be made that the proposed research meets the following criteria in consideration of the need to satisfy scientific and scholarly merit requirements:
- A.** The research uses procedures consistent with sound research design.
 - B.** The research design will allow the proposed research question to be answered.
 - C.** The knowledge to be gained from the research is sufficiently important from the research or training perspective.
 - D.** The risk/benefit relationship is acceptable.

When the IRB does not have sufficient expertise, the Board will utilize a consultant [HRPP Policy #[2.003](#)].

3.1 Other UMCP Committees Providing Review

3.2 Institutional Biosafety Committee (IBC)

Federal law requires the establishment of an [Institutional Biosafety Committee](#) (IBC) at institutions where the research involves recombinant DNA molecules or human testing of materials containing recombinant DNA (including gene transfer and some vaccine trials.)



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.006

Title: Scientific and Scholarly Merit Review of Projects

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

At UMCP, the IBC is appointed by the Vice President of Administration and Finance. The committee consists of the Chairman, faculty, and community representatives. Two community members, with no UMCP affiliation other than membership on the IBC, are required and appointed to represent the interest of the surrounding community with respect to health and the protection of the environment.

The IBC represents collective expertise and research experience in recombinant DNA, infectious agents and biological safety in experiments, which may pose potential risks to human health or to the environment.

The IBC is responsible for ensuring that research conducted at UMCP is in compliance with the National Institutes of Health Guidelines for Research Involving Recombinant DNA, drafting campus Biosafety policies and procedures as well as reviewing individual research proposals for Biosafety concerns.

The PI is required to inform Office of Sponsored Programs of all recombinant DNA experiments that are not exempted from the National Institutes of Health guidelines. The projects must be reviewed and approved by the IBC prior to the initiation of the research using IBC application form and review process.

PIs who wish to perform research using bio-hazardous materials must submit an application to the IBC. Applications are required for research that involves the use of: Recombinant DNA, Vaccine/Gene Therapy, Infectious Agents, and Toxins.

If the PI is working with potentially infectious agents and human participants, IBC review is necessary in addition to review by the IRB. Final approval by the IRB is contingent upon final approval by the IBC and the Radiation Safety Committee. Normally, IBC review will precede IRB review and the assigned IRB reviewer is notified by HRPP staff of any concerns expressed by the IBC. If, however, IBC review follows IRB review and the IBC identifies concerns that merit review by the full IRB, the protocol will be referred for re-review at a convened meeting.

The IBC is authorized by the Vice President of Administration and Finance to limit or



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.006

Title: Scientific and Scholarly Merit Review of Projects

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

suspend any research that does not comply with UMCP Biosafety policies and procedures.

The HRPP Director serves on the IBC as an ex-officio member to facilitate communication between committees.

3.3 Radiation Safety Committee (RSC)

The RSC operates under the auspices of the Department of Environmental Safety at UMCP. The RSC is charged with ascertaining that all experimental or research uses of radioactive materials and/or ionizing radiation in or on human beings conform to the currently accepted radiation protection regulations and practices, and the UMCP Radioactive Material License on file with the Maryland Health and Human Services System.



1.0 Purpose

The purpose of this SOP is to describe the IRB and Office of Research Administration review process for determining PI conflict of interest.

2.1 Definitions

2.2 Financial Interest Related to Research means financial interest in the sponsor, product, or service being tested, or competitor of the sponsor or product or service being tested.

2.3 Significant Financial Interest means anything of monetary value, either from the sponsor or entities other than the sponsor, including but not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (stocks, stock options or other ownership interests); and intellectual property rights (patents, copyrights and royalties for such rights). This includes:

- A. Ownership interest, stock options, or other financial interest related to the research either from the sponsor or entities other than the sponsor that: amounts to more than \$0 when aggregated for the immediate family OR (stock) is not publicly traded on a stock exchange OR is not governed by an arrangement that would prevent any outcome of the research to possibly affect the value of the ownership interests OR exceeds 5% interest in any one single entity when aggregated for the immediate
- B. Compensation related to the research that: amounts to more than \$0 over the past year when aggregated for the immediate family OR is not governed by an arrangement that would prevent any outcome of the research to possibly affect the amount of compensation.



- C. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
 - D. Board or executive relationship related to the research, regardless of compensation.
- 2.4** Ownership interest means any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a non-publicly traded corporation), or any equity interest in a publicly traded corporation during the time the investigator is carrying out the study and for 1 year following completion of the study.
- 2.5** Immediate family member is anyone having a relationship to a person (whether by blood, law, or marriage) as a spouse, parent, child, grandparent, grandchild, stepchild, or sibling.
- 2.6** Compensation affected by the outcome of the research means compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.
- 2.7** Proprietary interest means property or other financial interest in the product including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- 2.8** Payments made by an organization to the investigator or the institution exclusive of the costs of conducting the research during the time the investigator is carrying out the study and for 1 year following the completion of the study. This includes, but is not limited to:
- A. Income from seminars, lectures or teaching engagements
 - B. Income from service on advisory committees or review panels
 - C. Grants to fund ongoing research
 - D. Compensation in the form of equipment



E. Retainers for ongoing consultation

2.9 Patent is an official written document securing to an inventor for a term of years the exclusive right to make, use, or sell an invention.

2.10 Royalty is compensation for an invention.

2.11 Key research personnel are those individuals who: 1) obtain consent from human subjects; 2) recruit human subjects; or 3) evaluate the response of human subjects.

3.1 Policy

It is the policy of the IRB that the Principal Investigator, the responsible party for the research, declares all significant financial interests. These policies and procedures apply to financial conflicts of interest and are guided by Code of Federal Regulations (Title 42 of the Code of Federal Regulations (CFR) Part 50 Subpart F) that promotes objectivity in research to ensure conflict of interests do not adversely affect the protection of participants or the credibility of UMCP's Human Research Protection Program (HRPP). Actual or perceived conflicts of interest should be eliminated where feasible, and effectively disclosed and managed when elimination is not feasible.

3.2 The IRB Initial Application Part 2 Template includes a COI disclosure section for the PI.

3.3 When the research involves human participants, the Chair of the IRB, or his/her designee, will participate in the initial review, as necessary, to determine if there is a potential financial conflict of interest.

Any investigator, key personnel, and/or their immediate family, who hold a significant financial interest, shall be deemed to have a potential conflict of interest, which requires review by the Conflict Of Interest in Research Committee (COIR) and the IRB.

3.4 When it is determined that the principal investigator or other key personnel have a significant financial interest related to the research, the individual must describe the



financial interest and any steps planned to prevent the financial interest from interfering with the design, conduct, or reporting of the research, including interfering with the protection of participants.

- 3.5** The COIR Officer will review all potential conflicts of interest and recommend an appropriate management plan. The COIRC will review and approve the COIR management plan.
- 3.6** The COIRC will perform its review prior to IRB review. The IRB, in addition to the IRB application form and supporting documents, will be provided with a copy of the COIR management plan.
- 3.7** The full IRB will review the potential conflict of interest and the COIR management plan in terms of the Board's obligation to ensure protection of the rights and welfare of human participants. This charge includes authority to:
- A.** Ensure disclosure in the consent document of any financial interests of the investigator that are judged by the IRB to be material to the participant's decision whether or not to participate in research.
 - B.** Ensure there is an appropriate plan for monitoring of the research, which may involve observation of the consent process, auditing of records, and interim reporting of research results to the IRB.
 - C.** Require informed consent be obtained by a qualified individual other than the principal investigator.
- 3.8** The IRB will forward the results of the IRB review, including any modified management plan back to the COIR Officer. The COIRC will review and approve the COI management plan and the plan will be carried out by the COIR Officer. However it should be noted that the COIRC may not delete any IRB COIR management recommendation within the authority of the Board as previously specified under 3.7 A, B, and C.



1.0 Purpose

The purpose of this SOP is to describe the qualifications and responsibilities of personnel involved in the conduct of human participant research.

2.1 Policy

It is the policy of the IRB that all personnel involved in the conduct of human participant research must possess the required experience, skill, and appropriate licensure.

2.2 All research personnel listed on the IRB application are required to complete Human Subjects Protection training through the CITI program (HRPP Policy #[3.009](#)). Non-UMCP personnel may link equivalent human subject research training or complete CITI Training under UMCP. The IRB will not approve new projects, changes, or annual reviews of existing projects until all listed personnel in the IRB application have been trained.

2.3 The following are the classifications of study personnel:

A. **Principal Investigator (PI)**

This individual assumes overall responsibility for the study design, and as such, for the development and submission of the protocol to the IRB; the obtaining of informed consent/assent from prospective participants by all authorized personnel listed on the application; the conduct of the research; and the publication of the findings that ensue from data collection.

Only one (1) individual may be listed as a PI for a study.

Students may function as the PI, and therefore may be listed on the protocol as PI. However, a UMCP faculty advisor must supervise the project and be listed on the project as the supervising investigator. UMCP Staff members cannot supervise the student.

B. **Supervising Investigator(s) & Other Key Personnel**

These individuals assume shared responsibility for the project design, and as such, contribute substantively to the development and submission of the protocol to the IRB, the obtaining of informed



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.008

Title: Qualifications and Responsibilities of Research Personnel

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

consent/assent from prospective participants, the conduct of the research, and the publication of the findings that ensue from data collection.

C. Participating Personnel

These individuals are faculty or graduate students who have a limited or no role in project design. Therefore, these personnel typically do not participate in the development and submission of the IRB protocol.

Regardless of their specific duties on the project, participating personnel must have sufficient knowledge about the protocol and study design to effectively perform their respective project role.



1.0 Purpose

The purpose of this SOP is to describe training requirements for all personnel involved in conducting human participant research.

2.1 Policy

It is the policy of the IRB that all personnel involved in the conduct of exempt and non-exempt human participant research must receive training in the protection of human participants.

2.2 Collaborative Institutional Training Initiative(CITI)

Training in the protection of human participants is primarily accomplished through completion of this web-based training program.

A. Personnel to be Certified

Research personnel listed on the IRB application and consent document(s) by name must complete either the *Social & Behavioral Research – Basic/Refresher Course* or *Biomedical Research – Basic/Refresher Course*. Research personnel are classified as follows:

- Principal Investigator
- Co-Investigator
- Faculty Advisor
- Participating Personnel (including students engaged in human participant research)

B. Student Research

All graduate students conducting human participant research (exempt and non-exempt) and undergraduates who have responsibility for project design and integrally involved in data collection must take the Basic CITI course.

C. External Investigators

The IRB will accept certificates of training from other institutions when research personnel include external investigators or



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.009

Title: Required Training

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

subcontract recipients who have been trained elsewhere and are under the legal jurisdiction of that institution with respect to compliance with federal regulations. A copy of any certification must be provided to the HRPP office.

D. New Research Personnel

All new employees serving as investigators, faculty advisors, or participating personnel must complete CITI training prior to addition as research personnel to any research study. The IRB will accept certificates of training from prior institutions only if the other institution utilized the CITI training system.

E. IRB Approval

All research personnel must be CITI trained/certified prior to IRB review and approval of initial research applications and continuing review applications. The Completion Report must be linked to the submitted IRB Application in IRBNet. **NOTE:** Current project personnel whose prior certification may have lapsed must renew certification prior to IRB review and approval of any new application of annual continuing review.

F. Access to the CITI Training Program

A link to the CITI Training Program is available through the HRPP website (<https://research.umd.edu/irbtraining>). Following registration, individuals will be able to immediately access the system.

G. Test Data Confidentiality

Individual test scores are confidential. The webmaster and staff supporting the distance learning software have access to individually identifiable quiz scores.

Additionally, the IRB staff will have access to the individual test scores to determine if the test taker achieved the minimum passing score. Aggregate, anonymous quiz data will be used by course faculty to help improve course content and quiz questions. There will be no further disclosure of individually identifiable quiz results or aggregate institutionally identifiable results beyond that mentioned above.

**H. Passing Score**

The IRB requires a passing score of 80% overall to receive CITI certification.

I. CITI Certification Renewal

Certification for training using the CITI course is valid for 3 years from the original date of completion. Certification must be renewed at that time for the individual to be listed as an authorized study personnel in new IRB applications or continuing review forms. Reminder emails will be sent as a courtesy prior to expiration. Certification renewal is available through the CITI Refresher Course. The IRB requires a passing score of 80% overall to receive a renewal of CITI certification.

2.3 Additional Training Requirements

- A.** All research personnel listed on the IRB application are expected to read The Belmont Report, which is posted on the OHRP site (<https://www.hhs.gov/ohrp/>).
- B.** All research personnel listed on the IRB application are expected to read UMCP IRB policies, which are applicable to their research and, which can be accessed on the [HRPP website](#).
- C.** All research personnel listed on the IRB application are expected to be reasonably familiar with the requirement of Health and Human Services regulations at 45 CFR §46, which can be accessed on the OHRP website (<https://www.hhs.gov/ohrp/>).

2.4 Additional Available Training

The HRPP website, which is regularly updated and contains links to OHRP and other websites, serves as the primary educational resource and outreach tool for the campus. In addition, the IRB staff conducts workshops on an on-going basis for investigators, project coordinators, and students. IRB Policy updates appear on the HRPP website.



1.0 Purpose

The purpose of this SOP is to describe the criteria that the IRB will use at both initial and continuing review in determining the need for 1) IRB review more often than annually, 2) increased monitoring, and 3) verification from sources other than the investigator that no material changes have occurred since previous IRB review.

2.1 Policy

It is the policy of the IRB that that all non-exempt research will be assessed at both initial and continuing review in accordance with the requirements set forth by Health and Human Services regulations at 45 CFR §46.108(3)(i) and 45 CFR§46.109(e)(f).

2.2 Increased Monitoring and/or Interim Continuing Review

- A.** Unless specifically waived by the IRB, research that meets any of the following criteria will require review more often than annually:
1. Significant risk to research participants (e.g., death, permanent or long-lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the participants.
 2. The involvement of especially vulnerable populations likely to be subject to coercion (e.g., institutionalized psychiatric patients, incarcerated minors); or
 3. A history of serious or continuing non-compliance on the part of the PI.
- B.** The following factors will determine which studies require review more frequently than on an annual basis:
1. The probability and magnitude of anticipated risks to participants.
 2. The likely medical condition of the proposed participants.
 3. The overall qualifications of the PI and other members of the research team.
 4. The specific experience of the PI and other members of the research team in conducting similar research.



5. The nature and frequency of adverse events observed in similar research at this and other institutions.
 6. The novelty of the research making unanticipated adverse events and/or serious problems more likely; and/or
 7. Any other factors that the IRB deems relevant.
- C. When the IRB determines the need for increased monitoring, this oversight may be accomplished by either: 1) submission of interim reports by the PI, or 2) auditing of investigator records by the Research Compliance Analyst. The PI will be notified of these requirements in writing.
- D. If the IRB determines the need for more frequent continuing review, the PI will be notified in writing and the IRB approval period will be set accordingly. Based on the criteria factors of **2.1A** and **2B**, the IRB shall determine whether the research shall be reviewed more often than annually.

2.3 Independent Verification

The following circumstances may require verification from sources other than the investigator that no material changes have occurred since the previous IRB review:

- A. History of noncompliance.
- B. Recurrent delays in submitting amendments.
- C. High number of IRB approval expirations.
- D. Failure to respond to IRB review letters or other correspondence in a timely manner.

When the IRB determines that verification from sources other than the investigator is necessary, the Research Compliance Analyst and/or IRB member(s) will perform the necessary verification by conducting an audit.



UNIVERSITY OF MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.011

Title: Certificate of Confidentiality

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 16, 2020

1.0 Purpose

The purpose of this SOP is to describe the process for applying for a Certificate of Confidentiality from the National Institutes of Health.

2.1 Policy

It is the policy of the IRB that a Certificate of Confidentiality may be required for certain research proposals where the potential of disclosure of sensitive, personally identifiable information creates significant risk of harm or damage to the participant.

2.2 Purpose

- A. Certificates are issued by the National Institutes of Health for the purpose of protecting identifiable research information from compelled disclosure. The certificate allows the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.
- B. Federal funding of the research is not a prerequisite.
- C. A Certificate does not prevent voluntary disclosures such as limited disclosure to protect the participant or others from serious harm, as in cases of child abuse.
- D. A research protocol cannot rely on a Certificate to withhold data if the participant consents in writing to the disclosure.

2.3 Applicable Research

- A. The project must be categorized as research [HRPP Policy#[3.001](#)].
- B. The research must be IRB-approved.
- C. The information collected must be “sensitive” (e.g., disclosure will involve significant harm or damage to the participant).



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.011

Title: Certificate of Confidentiality

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 16, 2020

- D. Personally identifiable information is collected during the research.
- E. The investigator and/or the IRB determine that a Certificate is necessary to minimize risk to participants.
- F. Certificates are issued for single, well-defined research projects rather than groups or classes of projects. Occasionally a Certificate can be issued for cooperative multi-site projects. A coordinating center or “lead” institution designated by the National Institutes of Health program officer can apply on behalf of all institutions involved in the protocol. The lead institution must ensure that all participating institutions conform to the application assurances and inform participants appropriately about the Certificate, its protections, and circumstances in which voluntary disclosures would be made.
- G. National Institute of Health funded researchers are automatically issued a Certificate of Confidentiality through their award. Other Department of Health and Human Services agencies (FDA, CDC, SAMSHA, HRSA, IHS) issue Certificates of Confidentiality for research they fund.

2.4 Sensitive Research Categories

- A. Information relating to sexual attitudes, preferences, or practices.
- B. Information relating to the use of alcohol, drugs, or other addictive substances.
- C. Information pertaining to illegal conduct.
- D. Information that, if released, could damage a participant’s financial standing, employability, or reputation within the community.
- E. Information that would normally be recorded in a patient’s medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.
- F. Information pertaining to an individual’s psychological well-being or mental health.
- G. Genetic information.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.011

Title: Certificate of Confidentiality

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 16, 2020

2.5 Application Process

- A. Principal investigators conducting research collecting sensitive human participant information may apply for a Certificate of Confidentiality from the National Institutes of Health.
- B. In addition to the completed application, the PI will be required to provide documentation of IRB approval and a copy of the informed consent form(s) as it would read if a Certificate of Confidentiality is obtained (e.g., explains the Certificate, its protections and the circumstances in which voluntary disclosures might be made).
- C. Both the PI and the IO are required to sign the Certificate application.
- D. Detailed instructions and further information may be found on the National Institutes of Health website:
<https://humansubjects.nih.gov/coc/apply>



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.012

Title: External IRB Approval of Cooperative Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

1.0 Purpose

The purpose of this SOP is to describe the conditions under which the IRB will accept external IRB review and approval of cooperative research.

2.1 Policy

It is the policy of the IRB that, in recognition of the importance of cooperative, multi-site research and the potential for duplication of effort, the IRB may agree to enter into a joint review arrangement and rely upon the review of another qualified IRB, in accordance with Health and Human Services regulations at 45 CFR §46.114.

2.2 Conditions

- A. UMCP faculty, staff, or students will conduct the research solely at an external institution under the authority of that institution's IRB.
- B. The external institution has accepted full responsibility to protect the rights and welfare of all participants enrolled within its institution, in accordance with Health and Human Services regulations at 45 CFR §46.
- C. The external institution has a Federal Wide Assurance (FWA) approved by OHRP.
- D. The UMCP IRB has received a copy of the external IRB Approval Letter, a summary of UMCP investigator roles, and may request other project documents as needed.

2.3 IRB Review

The UMCP IRB Chair will review the submission and is authorized to accept external IRB approval. The full IRB will be notified accordingly.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.012

Title: External IRB Approval of Cooperative Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

2.4 IRB Authorization Agreement

- A.** The external IRB will be notified of the decision to accept external IRB approval.
- B.** An IRB Authorization Agreement will be created and signed by the HRPP Director or Designee from each institution.

2.5 Multi-site Research

When UMCP is the lead in a cooperative multi-site human participant research project, the principal investigator must go through the usual IRB application and review process. External institutions must make an independent decision about whether to accept UMCP's determinations.

**1.0 Purpose**

The purpose of this SOP is to describe the requirements for retention and security of research records.

2.1 Policy

It is the policy of the IRB that the research record maintained by the IRB and PI must: 1) contain an accurate and complete account of the conduct of the study; 2) be maintained and stored securely; and 3) be retained for the required amount of time following completion of the research in accordance with Health and Human Services regulations under 45 CFR §46.115(b), and sponsor requirements as applicable.

UMCP Policy also applies UMCP Policy [<http://www.dbs.umd.edu/records/schedule/>]. Item 84 pertains to investigator record retention. Item 197 pertains to IRB record retention.

2.2 Research Record

The research record must include, but is not limited to:

- A.** Initial proposal: 1) IRB application; 2) detailed protocol; 3) grant (if applicable); 4) consent forms (if applicable); 5) case report forms (if applicable)
- B.** Applications for continuing review and corresponding documents
- C.** Requests for change to the project and/or consent forms
- D.** Reports of adverse events and unanticipated problems involving risk to the participant or others
- E.** Single participant protocol deviation and retrospective protocol by the violation reports
- F.** Issues of noncompliance
- G.** IRB-PI correspondence



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.013

Title: Research Records Retention and Security

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

- H. Any other protocol-related documentation not covered by the above. The PI also will maintain copies of sponsor contracts and correspondence (if applicable) and subject files that should contain: 1) signed consent documents; 2) laboratory results and 3) other applicable information.

2.3 Security of Research Records

- A. All research records must be maintained and stored securely, in a manner that protects participants' privacy and confidentiality by preventing unauthorized access (e.g., locked file cabinets and offices; password protected electronic devices, and use of study participant identifiers known only to research staff).
- B. All research databases must comply with UMCP Information Security policies and procedures relating to the safeguarding of electronic confidential information [<https://it.umd.edu/security>].
- C. Records are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

2.4 Retention of Research Records

- A. Social science, behavioral and biomedical research records must be retained for at least seven (7) years beyond the termination of the project, or longer as required by sponsors. However, research data should be de-identified as soon as possible. This includes destroying any links to identifiable research data.
- B. If the investigator resigns from UMCP before the end of the designated period, the department of record must maintain the research records unless otherwise specified. The investigator, however, may have a copy of the research records in accordance with applicable UMCP records policies.
- C. If a project is cancelled without participant enrollment, records are retained for at least three (3) years after cancellation.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.014

Title: PI Disagreement with IRB Determinations

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

1.0 Purpose

The purpose of this SOP is to describe the procedure a PI may take to express disagreement with IRB decisions.

2.1 Policy

It is the policy of the IRB that a PI has the right to disagree with IRB decisions and may seek resolution. However, appeals of disapproved projects will not be considered.

2.2 The results of the IRB expedited or full board review will be conveyed to the PI by the IRB Chair and/or IRB staff through written electronic correspondence. Individual IRB members should not discuss the results of the IRB review with the PI unless agreed upon by the IRB Chair or the IRB.

- A.** If a PI disagrees with the IRB's written decision, he/she is encouraged to contact the HRPP office and/or the IRB Chair and provide a written response detailing justification for the disagreement.
- B.** If the disagreement is related to a substantive human protection issue and the protocol was reviewed by the full IRB, the protocol will be referred to the full IRB.
- C.** Appeals of disapproved research projects will not be considered.
- D.** If the disagreement does not represent a substantive human protection issue, the IRB Chair will seek a resolution.
- E.** If resolution of the disagreement requires direct interaction with the, the PI may be invited to attend a portion of the IRB meeting to address Board concerns.

2.3 Any PI who believes there is a conflict of interest on the part of any IRB member relative to his/her protocol is encouraged to contact the IRB Chair and/or the IO. All necessary steps will be taken to immediately resolve the problem.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.014

Title: PI Disagreement with IRB Determinations

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

- 2.4** Investigators who have concerns or suggestions regarding the Institution's human research protection program should convey them to the Institutional Official or other responsible parties (e.g. college dean, department chair) regarding the issue, where appropriate. The Institutional Official will investigate the issue, and where deemed necessary, convene the parties involved to form a response to the investigator to make necessary procedural or policy modifications, as warranted. In addition, the Chair of the IRB or the HRPP Director will be available to address investigators' questions, concerns, and suggestions.



UNIVERSITY OF MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.015

Title: Compensation for Research Participants
Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

1.0 Purpose

The purpose of this SOP is to describe compensation for research participants.

2.1 Policy

It is the policy of the IRB that compensation for research participants may be acceptable if: 1) the possibility of coercion or undue influence is minimized, and 2) the compensation is considered a recruitment incentive, not a benefit, in accordance with Health and Human Services regulations at 45 CFR §46.116.

2.2 Requirements

- A. Compensation for participation is not an obligation of the researcher toward the participant. Compensation may be offered but is not required.
- B. Participation in research should not require financial sacrifice but should be revenue neutral for participants.
- C. Compensation should not be used as a “benefit” to offset risks (either quantitative or qualitative) associated with the research.
- D. Generally, compensation should be based upon the premise that participation in research requires time and effort from the participant. Compensation, when offered, should be based on a reasonable consideration of the duration of time spent in preparation for, participation in, and recovery from, research interventions, in addition to the effort expended during the research activities.

Interventions are understood to include such elements as procedures performed, visits to a clinic or research setting, phone interviews, or surveys completed. If appropriate, such compensation should include all parties involved. For example, if a family member is required to be present to drive a research participant home after a procedure, his/her time can be compensated.



- E. Compensation above these levels must be justified by the investigator and must comply with the enumerated principles.
- F. In order to minimize the risk that cumulative compensation for prolonged participation could unduly influence participation, the compensation plan should be described clearly in the consent form, including the portion of compensation that will be received at each study milestone, as well as the total amount to be paid. Scientific rationale and justification for the specific compensation plan needs to be provided and comply with the enumerated principles.

Credit for payment is to accrue as the study progresses and not be contingent only upon the participant completing the study. Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

- G. Payments for involvement of young minors (<16 years) in research should not be made directly to the minor. Depending on scientific rationale and justification, minors can be offered an age appropriate item through their parents for their participation, such as a toy or gift certificate. With appropriate rationale and justification, 16- through 18-year-olds may be compensated directly.
- H. UMCP IRB does not allow payment in exchange for referrals of prospective participants (finder's fees), nor does it allow payments to the organization or research staff designed to accelerate recruitment that were tied to the rate or timing of enrollment (bonus payments).

2.3 Use of Raffle/Lottery

The IRB will consider such plans for participant compensation on a case-by-case basis, with appropriate scientific rationale and justification provided by the PI. Under certain conditions, a lottery or raffle can be used as a recruitment incentive. In these cases,



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 3.015

Title: Compensation for Research Participants

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

lotteries/raffles are not participant compensation, per se.

2.4 Extra Credit

Extra Credit may be offer to students as compensation. However, the credit should be reasonable and not so large as to unduly induce potential participants. In the case where a specific class is identified as the population and extra credit is offered as compensation, an alternate method to obtain this extra credit must be identified for those in the class who do not wish to participate in the research. This is to avoid unduly inducing potential participants.



1.0 Purpose

The purpose of this SOP is to describe the IRB requirements for recruitment of participants through advertisements.

2.1 Policy

It is the policy of the IRB that all participant recruitment strategies including printed newspaper advertisements, bulletins, fliers, multimedia, radio, and television must be reviewed and approved before they can be used to recruit potential participants.

2.2 Design

Advertisements should be limited to information a potential participant may need to determine if they are interested and eligible to participate in a study.

A. Appropriate items to include in an advertisement are:

1. Name and address of the investigator and associated institution
2. Purpose of the research
3. Eligibility criteria (in shortened form)
4. Listing of realistic benefits to the participant (if any)
5. Time or other commitments required from the participant
6. Location of the research, contact person, and phone number for further information
7. If applicable, incentives, which are intended to motivate the potential participant to consider participating in the research project, should be described (e.g., direct payment, lottery)

B. The following are not permitted to be included in advertisements:



1. State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
 2. Make claims, either explicitly or implicitly that the research procedures are safe or effective for the purposes under investigation.
 3. Include any exculpatory language.
 4. Overemphasis of payment for participation.
- C. Printed advertisements (e.g., newspaper ads and bulletins) should use appropriate font size and bolding to ensure the prospective participant is not misled by having their attention inappropriately drawn to a particular section of the advertisement.
- D. In the case of newspaper ads, the investigator should ensure that the layout and font size approved by the IRB is reflected in the final published copy.

2.3 Submission of Advertisements

Draft copies of all advertisements including radio and television scripts must be submitted to the IRB for review and approval. An advertisement may be reviewed by either the full IRB or by the expedited continuing method if it qualifies in accordance with Health and Human Services regulations at 45 CFR §46.110(b) (1) and (2).

2.4 IRB Record of Advertisements

The investigator should provide a copy of all recruitment advertisements to the IRB. All bulletins posted at the Institution must be kept on file in the IRB record.

2.5 The IRB review will include:

- A. The information contained in the advertisement.
- B. The mode of its communication
- C. The final test copy of printed advertisements.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 3.016

Title: Recruitment of Participants through
Advertisements

Section: *IRB Membership & Standard Operating
Procedures*

Date: December 5, 2017

Reviewed: September 16, 2020

D. The final audio/video taped advertisements.

The IRB ensures that advertisements do not emphasize the payment or the amount to be paid by such means as unduly large or bold type. A final copy of the recruiting advertisement must be sent to the IRB upon final printing or publication.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 4.001

Title: Exempt Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: October 1, 2020

1.0 Purpose

The purpose of this SOP is to describe the process for determining whether a research proposal is eligible for exempt status.

2.1 Policy

It is the policy of the IRB that all proposed exempt research is reviewed by the IRB staff, in consultation with the IRB Chair or HRPP Director, to determine that the research meets at least one of the categories of exemption from federal regulations for protection of human research participants in accordance with Health and Human Services regulations at 45 CFR §46.104. Exempt Categories

2.2 Exempt Categories

- A. Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- B. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
 - i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects
 - ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 4.001

Title: Exempt Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: October 1, 2020

readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

NOTE: *Projects involving oral history typically are not considered research unless the project a) utilizes a “systematic investigation” with analysis of data to answer a scientific question and b) are designed to develop or contribute to generalizable knowledge. If unsure, submit a Human Subject Research Determination Form through IRBNet.*

- C. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria (i-iii) is met:
- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
 - iv. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 4.001

Title: Exempt Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: October 1, 2020

offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

- v. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

- D. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - i. The identifiable private information or identifiable biospecimens are publicly available;
 - ii. The information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 - iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 4.001

Title: Exempt Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: October 1, 2020

private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

NOTE: *All of the data must exist prior to the start of the research for this exemption to apply.*

- E.** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
- i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 4.001

Title: Exempt Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: October 1, 2020

projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

- F.** Taste and food quality evaluation and consumer acceptance studies:
- i. If wholesome foods without additives are consumed, or
 - ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- G.** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
- H.** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
- i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
 - ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
 - iii. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 4.001

Title: Exempt Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: October 1, 2020

the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

NOTE: Research which involves photographing, audiotaping, or videotaping of participants during the research may be granted an exemption with some discretion as it relates to identifiable information or sensitivity of the research. Projects involving photographing, audiotaping, or videotaping will be reviewed on a case by case basis to determine the risk in relation to the identifiable nature of the photographs, audio, and/or video recordings along with the sensitivity of the questions being asked. The use of scrambling technologies, such as voice alteration or blurring/masking also will be taken into consideration.

2.3 Ineligible Research

- A. Sensitive survey research that is identifiable where the disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
- B. The research involves survey, interviews, or participant observation with children.
- C. Research involving prisoners, persons who are decisionally or psychologically impaired, who are economically or educationally disadvantaged and other participant populations determined to be vulnerable upon review.

2.4 Ethical Considerations

Although exempt research is not covered by the federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report. The individual making the determination of exemption may require additional protections for participants in keeping with the guidelines of the Belmont Report.

**2.5 Process of Review**

- A.** The PI must complete and submit the IRB application form online via IRBNet.
- B.** The Research Compliance Analyst, in consultation with the IRB Chair or Director will determine whether an exemption should be granted. The complete exempt protocol application will be reviewed [HRPP Policy [2.014](#)]
- C.** All exempt research involving human participants must maintain an ethically appropriate standard, which serves to protect the rights and welfare of the participants. This involves informed consent as necessary and confidentiality of data. In some exempt research projects, standard written informed consent must be obtained.
- D.** If the HRPP office determines that the research qualifies for exempt status, the investigator will be notified within approximately two weeks following receipt of the IRB application.
- E.** Once an Exempt determination has been made, the project will not require annual review. Projects that qualify as exempt are valid for three years. At that point, a Continuing Review must be submitted if the project will continue past the expiration date.
- F.** All modifications of protocols including exempt research must be submitted to the IRB. Exempt research, which requires modification during the course of the study whereby it is no longer exempt, must be resubmitted to the IRB prior to implementation of the modification.
- G.** The HRPP office reserves the right to refer applications for exempt research to either the expedited review procedure or the full IRB for review as necessary.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 4.002

Title: Expedited Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: October 1, 2020

1.0 Purpose

The purpose of this SOP is to describe the expedited review process for initial and continuing review.

2.1 Policy

It is the policy of the IRB that expedited review will be conducted in accordance with Health and Human Services regulations at 45 CFR §46.110. Protocols reviewed and approved by the expedited method must: **1)** present no greater than minimal risk; **2)** involve procedures listed in one or more of the categories specified in the Federal Register (<http://www.hhs.gov/ohrp/policy/expedited98.html>); and **3)** meet all the criteria specified in Health and Human Services regulations 45 CFR §46.111. Expedited review may be used to perform continuing review in accordance with HRPP Policy [#11.001](#).

- A.** In general, expedited review will not be used for research involving prisoners. However, in certain cases, the prisoner representative may review a new project or a transaction involving changes to a currently approved project involving prisoners or prisoner data. This decision will be made based on the risk benefit ratio of the project and/or the impact the changes may have on the project.

The prisoner representative will provide feedback and the transaction will be sent to the IRB Chair for final determination. The Chair may determine to approve the transaction, require modifications, or forward to the full committee for review and discussion.

- B.** Three (3) applicable criteria must be met for the initial or continuing review using the expedited continuing procedure, these include:
- 1.** The current and future research procedures present no more than minimal risk to participants [Not required for category (8) (b)].



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 4.002

Title: Expedited Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: October 1, 2020

2. The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. [Not required for category (8)(b)].
3. The research is not classified.

2.1. Expedited Categories

- A. Clinical studies of drugs and medical devices only when condition 1. or 2. is met:
 1. Research on drugs for which an IND is not required.
 2. (a) Research on medical devices for which an IDE application is not required; or (b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- B. Collection of blood sample by finger stick, heel stick, ear stick, or venipuncture as follows:
 1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 mL in an 8 week period and collection may not occur more frequently than 2 times per week; or
 2. From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 4.002

Title: Expedited Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: October 1, 2020

NOTE: Health and Human Services regulations at 45 CFR §46.402(a) define children as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.”

- C.** Prospective collection of biological specimens for research purposes by non- invasive means.

Examples: Hair and nail clippings in a non-disfiguring manner; deciduous teeth (at time of dental exfoliation) or if routine patient care indicates a need for extraction; permanent teeth if routine patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax, or by applying a dilute citric solution to the tongue; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.

- D.** Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice (excluding procedures involving x-rays or microwaves). Where medical devices are employed, they must be cleared or approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant’s privacy; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate for the age, weight, and health of the individual.

- E.** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).



Policy #: 4.002

Title: Expedited Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: October 1, 2020

NOTE: Some research in this category may be exempt from the Health and Human Services regulations for the protection of human participants. This listing refers only to research that is not exempt.

- F.** Collection of data from voice, video, digital, or image recordings made for research purposes.
- G.** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

NOTE: Some research in this category may be exempt from the Health and Human Services regulations for the protection of human participants. This listing refers only to research that is not exempt.

- H.** Continuing review of research previously approved by the convened IRB meets one of the following conditions:
 - 1.** Where (a) the research is permanently closed to the enrollment of new participants; (b) all participants have completed all research interventions; and (c) the research remains active only for long-term follow-up of participants, OR
 - 2.** Where no participants have been enrolled and no additional risks have been identified; OR
 - 3.** Where the remaining research activities are limited to de-identified data analysis

2.2 Expedited Review Process

- A.** The IRB staff will perform a pre-review of all applications which qualify for expedited review using the above Expedited Category descriptions and the OHRP-provided Criteria for Approval [[45 CFR §46.111](#)]. The IRB staff will obtain clarifications from the PI and request revision of applicable documents, if necessary.



Policy #: 4.002

Title: Expedited Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: October 1, 2020

- B. Once pre-review is completed, the IRB Chair will serve as the expedited reviewer. If necessary, one or more experienced IRB members designated by the IRB Chair will serve as expedited reviewer(s). An experienced member is defined as having greater than 6 months served on the UMCP IRB.
- C. The IRB Chair, HRPP Director, or assigned expedited reviewer, retains the right to refer any project transaction to the full IRB for review. However, reviewers may not disapprove expedited or exempt project submissions. A project transaction may only be disapproved by the full IRB.
- D. The expedited reviewer will utilize the IRB review criteria specified in HRPP Policy #[3.004](#) and [45 CFR §46.111](#). The reviewer using the expedited procedure evaluates and indicates whether the research undergoing initial or continuing review:
 1. Meets the three applicability criteria (Continuing Review);and
 2. Represents one or more approvable categories or research.
- E. After a project transaction is approved using the expedited procedure, the full IRB will be notified through listing the approvals on the next meeting agenda and documenting this report in the meeting minutes.
- F. All IRB Members can access expedited project documents and transactions via IRBNet and may make comments that can be presented at the full IRB meeting. Even if a project transaction has been approved using the expedited procedure, the full IRB reserves the right to require modification to the project documents warranted. Additionally, the full IRB can suspend or terminate the project or halt accrual if necessary.

2.3 Expedited Review Actions

A. Approval

No modifications required. All of the criteria for IRB approval specified in [45 CFR §46.111](#) have been satisfied. The investigator will be notified of approval in writing through IRBNet and is authorized to begin the project.

B. Approval with Specific Changes/Modifications

The investigator will be notified in writing through IRBNet as to the nature of the required modifications. Once the modifications have been addressed, the project will be sent to the IRB Chair/designee for final approval.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 4.002

Title: Expedited Research

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: October 1, 2020

C. Full Review

The project is referred to the full IRB for review.

2.4 Expedited Continuing Review

Review conducted under an expedited continuing review will be documented in the IRB determination letter to the PI. This documentation will include:

- A.** Identification of the specific permissible categories justifying the expedited continuing review.
- B.** Documentation of the review and action taken by the IRB Chair, or designated reviewer, and any findings required under the Health and Human Services regulations.



1.0 Purpose

The purpose of this SOP is to describe additional protections for vulnerable populations.

2.1 Policy

It is the policy of the IRB that the vulnerability of a potential participant population will be evaluated to ensure that appropriate protections are in place for any participant who may be vulnerable in accordance with Health and Human Services regulations at 45 CFR §46.111(a)(3).

Health and Human Services regulations at 45 CFR §46 provide special protections for prisoners (Subpart C) and children (Subpart D). 45 CFR §46 does not, however, include specific requirements for the protection of other vulnerable participant populations, such as decisionally impaired persons, terminally ill, economically or educationally disadvantaged persons, or other vulnerable populations. In these situations, the IRB, in consultation with the investigator, will determine the appropriate means to protect the rights and welfare of the individuals.

2.2 Definition

- A.** Vulnerable population is defined as an individual or group of individuals with limited autonomy (e.g., lacks independence in decision making for a variety of reasons) or is otherwise at increased risk compared to non-vulnerable individuals. Within any population of vulnerable participants, individuals will have different levels of vulnerability based on the level of capacity, circumstance, or condition affecting independent decision-making.

2.3 Categories of Vulnerable Populations

Vulnerable populations may be categorized according to the following groups:

- A.** Prisoners (Subpart C) (HRPP Policy#[5.003](#))
B. Children (Subpart D) (HRPP Policy#[5.004](#))
C. Pregnant women (Subpart B) (HRPP Policy#[5.002](#))
D. Fetuses and neonates (Subpart B) (HRPP Policy#[5.002](#))



- E. Decisionally impaired (HRPP Policy#[5.005](#))
- F. Comatose
- G. Terminally ill
- H. Economically disadvantaged
- I. Educationally disadvantaged
- J. Socially disadvantaged
- K. Employees and students (HRPP Policy#[5.006](#))
- L. Others as determined by the IRB and investigator

2.4 Factors Determining Vulnerability

- A. The nature of the research.
- B. The risks of the research.
- C. An increased probability of risk occurrence in the proposed population.
- D. Degree of autonomy, or limited autonomy, present in the proposed population.
- E. The clinical status of the proposed population.
- F. The educational status of the proposed population.
- G. The economic status of the proposed population.
- H. The presence of a support system (e.g., family and friends) for the proposed population.
- I. Cultural or social factors associated with the proposed population.

2.5 Additional Protections for Vulnerable Populations

Upon determining the vulnerability of an individual or population, the IRB and investigator will provide special protections against risk. These additional protections will include those specified by HRPP policies for research involving pregnant women, prisoners, children, or decisionally impaired participants.

Other additional protections, as deemed necessary by the IRB, may also be included:

- A. The use of an extended consent process.
- B. The use of a consent monitor.
- C. Appointment of a participant advocate.
- D. Involvement of the participant's family and/or friends.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 5.001

Title: Additional Protections for Vulnerable Populations

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 30, 2020

- E.** Limits placed on risk.
- F.** Exclusion from participating in the research.
- G.** Increased safeguards to protect privacy and confidentiality.
- H.** Increased monitoring of the research by the IRB or other mechanisms.
- I.** More stringent withdrawal criteria.
- J.** Longer study follow-up.



Policy #: 5.002

Title: Pregnant Women, Fetuses, and Neonates

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

1.0 Purpose

The purpose of SOP is to describe the IRB requirements for research involving pregnant women, fetuses, and neonates.

2.1 Policy

UMCP HRPP policies provide for additional protections for pregnant women, fetuses, and neonates involved in research. These policies are described below.

Research, which is funded by DHHS must satisfy the additional protections described in 45 CFR §46 subpart B. For all other research, additional protections are identical to those found in 45 CFR §46 subpart B except as indicated in 2.2 (A) (2) (b)

2.2 Definitions

- A. Pregnancy:** Period from confirmation of implantation of a fertilized egg within the uterus until the fetus has been delivered. Implantation is confirmed through a presumptive sign of pregnancy (e.g., missed periods or a positive pregnancy test). While confirmation may be in error, investigators must presume that a living fetus was present until evidence is presented to the contrary.
- B. Fetus:** The product of conception from implantation until delivery.
- C. Viable Neonate:** A neonate, after delivery that can survive to the point of independently maintaining heartbeat and respiration. (A viable neonate is covered by Health and Human Services regulations at 45 CFR §46, Subparts A and D.)
- D. Nonviable Neonate:** A neonate after delivery that, although living, is not viable.

2.3 IRB Review

In addition to review of research under Health and Human Services regulations at 45 CFR §46 (Subpart A), the IRB must provide special review of all behavioral/social science research where pregnant women, fetuses and/or neonates are involved.

**Policy #: 5.002****Title:** Pregnant Women, Fetuses, and Neonates**Section:** *IRB Membership & Standard Operating Procedures***Date:** December 5, 2017**Revised:** September 30, 2020**A. Research involving pregnant women or fetuses**

1. Pregnant women may be involved in research funded by DHHS if all of the following conditions are met:
 - a) Appropriate preclinical studies, including studies on pregnant animals and clinical studies involving non-pregnant women, have been conducted and provide data for assessing potential risks of pregnant women and fetuses.
 - b) Any risk to the fetus is caused solely by interventions that offer direct benefit for the woman or fetus, or if there is no prospect of direct benefit: 1) the risk to the fetus must not be greater than minimal and 2) the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
 - c) Any risk to the pregnant woman or the fetus is the least possible to achieve the research objectives.
 - d) Consent of the pregnant woman alone is required for research which:
 - 1) Offers direct benefit to the pregnant woman only, OR
 - 2) Will not directly benefit the woman or fetus but: a) there is no more than minimal risk to the fetus, and b) the purpose of the research is to develop important knowledge and the data cannot be obtained by any other means.
 - e) Consent of the pregnant woman and father is required if the research offers direct benefit to only the fetus. However, the father's consent is not required if he is unavailable, decisionally impaired, temporarily incapacitated, or if the pregnancy resulted from rape or incest.
 - f) The consent must fully disclose the reasonable foreseeable impact of the research on the fetus (e.g., risk).



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 5.002

Title: Pregnant Women, Fetuses, and Neonates

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

- g) Assent and parental permission for pregnant children participation in research must be obtained in accordance with Health and Human Services regulations 45 CFR §46, Subpart D (HRPP Policy #[5.004](#)).
 - h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
 - i) Individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
 - j) Individuals engaged in research will have no part in determining the viability of a neonate.
2. Pregnant women may be involved in research if all of the following conditions are met:
- a) Appropriate preclinical studies, including studies on pregnant animals and clinical studies involving non-pregnant women, have been conducted and provide data for assessing potential risks of pregnant women and fetuses.
 - b) If any risk to the fetus is caused solely by interventions that offer direct benefit for the woman or fetus, or if there is no prospect of direct benefit, the risk to the fetus must not be greater than minimal.
 - c) Any risk to the pregnant woman or the fetus is the least possible to achieve the research objectives.
 - d) Consent of the pregnant woman alone is required for research which:
 - 1) Offers direct benefit to the pregnant woman only, OR
 - 2) Offers direct benefit to the woman and fetus, OR
 - 3) Will not directly benefit the woman or fetus but there is no more than minimal risk to the fetus.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 5.002

Title: Pregnant Women, Fetuses, and Neonates

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

- e) Consent of the pregnant woman and father is required if the research offers direct benefit to only the fetus. However, the father's consent is not required if he is unavailable, decisionally impaired, temporarily incapacitated, or if the pregnancy resulted from rape or incest.
- f) The consent must fully disclose the reasonable foreseeable impact of the research on the fetus (e.g., risk).
- g) Assent and parental permission for pregnant children participation in research must be obtained in accordance with Health and Human Services regulations 45 CFR §46, Subpart D (see HRPP policy # [5.004](#)).
- h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
- i) Individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- j) Individuals engaged in research will have no part in determining the viability of a neonate.

B. Research involving placenta, dead fetus(s) or fetal material

Research involving the placenta, dead fetus, or fetal material after delivery may occur if all federal, state, or local laws and regulations are met. If any information associated with the material used in the research can be linked in any way to a living person, Health and Human Services regulations view the living person as a research participant and the research is subject to the regulations discussed in this policy.

C. Research not otherwise approvable

The Health and Human Services Secretary may conduct or fund research that the IRB does not feel meets the above policy if the following conditions are met:

**Policy #: 5.002****Title:** Pregnant Women, Fetuses, and Neonates**Section:** *IRB Membership & Standard Operating Procedures***Date:** December 5, 2017**Revised:** September 30, 2020

1. The IRB finds that the research, which will be funded by Health and Human Services, presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates, and the Secretary has determined through consultation with a panel of experts that the research does, in fact, meet the requirements of 45 CFR 46.204; OR
2. The Secretary determined that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of pregnant women, fetuses or neonates; is conducted in accord with sound ethical principles; and informed consent will be obtained. Note: For non-Health and Human Services funded research, involving pregnant women, fetuses, or neonates, the UMCP IRB will convene an equivalent panel of experts to advise the IRB.

2.4 Non-pregnant participants who become pregnant during research

If a participant becomes pregnant while actively participating in a research protocol, the investigator must:

- A. Determine if it is in the best interest of the pregnant participant to continue participating in the study or terminate participation in the study by completing the report on unanticipated problems or adverse event(s) involving risks to research participants or others, as described in HRPP Policy # [13.001](#).
- B. If it is in the best interest of the pregnant participant to remain in the study, adequate justification must be provided to receive IRB Chair approval for the participant to continue participation. If it is not in the best interest of the participant to continue, the participant's participation must be terminated.
- C. The study must be re-reviewed by the full IRB, as soon as possible, in consideration of this policy.



UNIVERSITY OF
MARYLAND

Human Research Protections

Policies and Procedures

Research Compliance Office

Institutional Review Board

Policy #: 5.002

Title: Pregnant Women, Fetuses, and Neonates

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

2.5 Documentation of IRB findings under Subpart B

The IRB will fully document compliance with Subpart B in the minutes of the IRB meeting by documenting the required determinations and protocol-specific findings justifying those determinations. The IRB Approval letter will also reflect compliance with Subpart B if applicable.



1.0 Purpose

The purpose of this SOP is to describe the procedure for research involving prisoners.

2.1 Policy

It is the policy of the IRB that the IRB will adhere to Health and Human Services regulations at 45 CFR §46, Subpart C provides for additional protections for prisoners involved in social/behavioral and biomedical research. These special protections include individuals who are prisoners at the time of enrollment in the study, as well as participants that become incarcerated after enrollment in a study. The IRB will apply Subpart C to all research involving prisoners regardless of funding, with one exception described under “Special Circumstances” (See section 2.3 below.)

2.2 Definitions

- A. **Prisoner** is defined by Health and Human Services regulations as any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures, which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
- B. **Minimal risk in prisoner research** is defined by Health and Human Services regulations as “the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.”

2.3 Permitted Research Involving Prisoners

Social/behavioral and biomedical research may involve prisoners as participants only if:

- A. The IRB has reviewed, approved, and determined that the research falls under one of the categories listed below in Section 2.7. In the case of DHHS-funded research, the IRB also must certify the approval to OHRP as described in 2.9.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 5.003

Title: Prisoners

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

B. The proposed research must fall within one of the following categories of permissible forms of research:

1. Study of the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents *no more than minimal risk*, and *no more than inconvenience* to the participants.
2. Study of prisons as institutional structures, or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk, and no more than inconvenience to the participants.

For the remaining two categories, it should be noted that final approval, as indicated below, rests with the Secretary of Health and Human Services with OHRP acting on behalf of the Secretary. Following IRB approval, the entire research proposal (including the IRB- approved protocol, any relevant Health and Human Services grant application or proposal, consent documents, any IRB application forms, and any other information requested or required by the IRB for initial review) will be submitted to OHRP. OHRP will consult with appropriate experts, including experts in penology medicine and ethics, and publish notice, in the Federal Register, of intent to approve such research. Health and Human Services, through OHRP, will issue its approval in writing to the IRB.

3. Research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems, such as alcoholism, drug addiction and sexual assault).
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the proposal is reviewed by OHRP (as discussed above).



For research which is not funded by Health and Human Services, neither certification to OHRP nor expert review for Categories 3 and 4 is required.

The IRB will only approve research, which fits one or more of the designated categories. In addition, the IRB will, at its discretion, convene an equivalent expert review body to review studies classified as 3 or 4.

2.4 Special Circumstances

A. **When a previously enrolled participant becomes a prisoner**

When a previously enrolled research participant becomes a prisoner and the relevant research was not reviewed and approved by the IRB in accordance with the requirements of Health and Human Services regulations at 46 CFR §46, Subpart C, the principal investigator must report the situation to the IRB immediately. Upon notification that a previously enrolled research participant has become a prisoner and the principal investigator wishes to have the prisoner continue to participate in the research, the IRB will promptly re-review the protocol in accordance with the requirements of Subpart C (as applicable).

All research activities and interventions for the now incarcerated prisoner-participant must stop until the protocol is reviewed under the requirements of Subpart C, except where the PI can justify that it is in the best interest of the participant to remain in the Health and Human Services -funded research study while incarcerated. The IRB Chair may determine that the participant may continue to participate until all the requirements of Subpart C are satisfied.

B. **When a potential participant is an adolescent detained in a juvenile detention facility**

If a potential participant is an adolescent detained in a juvenile detention facility, the individual is both a child and a prisoner. In such a case, Health and Human Services regulations at 45 CFR §46 Subpart C (prisoners involved in research) and 45 CFR §46 Subpart D (children involved in research) apply and will be satisfied.



C. When the PI indicates that the proposed participant population may have high risk of incarceration during the course of the study (but currently does not include prisoners)

The IRB may choose to review the proposal under Health and Human Services regulations at 45 CFR §46 Subpart C. However, it should be noted that predetermination of a participant population's potential for incarceration carries additional risks of violating the rights of justice and respect for persons. The definitions of minimal risk and the risk/benefit analysis may not truly be applicable to the participant population.

2.5 Expedited review of research involving prisoners

Health and Human Services regulations allow *expedited review*; however, OHRP recommends that the convened IRB review all research involving prisoners. Therefore, the IRB will normally not use *expedited review* for protocols, changes, or continuing review of research involving prisoners.

- A.** If the expedited review process is used for minor modifications to research, one of the two procedures described in 2.4.C.2 below may be used based on the type of modification.
- B.** Modifications involving more than a minor change reviewed by the convened IRB
 - 1.** The same procedure used for initial review must be used including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described in Section 2.6).
- C. Continuing Review**
 - 1.** The same procedure used for initial review must be used for continuing review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting (as described in Section 2.6).
 - a)** If no participants have enrolled, the research may receive continuing review using the expedited procedure under expedited category #8 (HRPP Policy #[4.002](#)).



2. Research involving interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
 - a) The prisoner representative must concur with the determination that the research involves no greater than minimal risk.
 - b) The prisoner representative must review the research as a reviewer, designated by the chair or consultant. This may be as the sole reviewer or in addition to another reviewer, as appropriate.
 - c) Review of modifications and continuing review must use the same procedures for initial review using this expedited procedure including the responsibility of the prisoner representative.

3. Research that does not involve interaction with prisoners (e.g. existing data, record review) may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
 - a) Review by a prisoner representative is not required.
 - b) The prisoner representative may review the research as a reviewer or consultant if designated by the IRB chair.
 - c) Review of modifications and continuing review must use the same procedures as initial review.

- D. When a participant is incarcerated temporarily while enrolled in a study
 1. If the temporary incarceration has no effect on the study, keep the participant enrolled.
 2. If the temporary incarceration has an effect on the study, handle according to the guidance in 2.4.A-2.4.C.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 5.003

Title: Prisoners

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

- 2.6** Research involving prisoners and exemption under 45 CFR §46.301(a). Health and Human Services regulations do not allow exemption of research involving prisoners (45 CFR §46.101(i), footnote 1).
- 2.7** IRB Membership Requirements In addition to federal requirement regarding any research involving human participants, the IRB will satisfy the following additional requirements when the research involves prisoners, regardless of funding source:
- A.** The majority of the members of the IRB will not have an association with the prison(s) involved in the study (excluding the prisoner members).
 - B.** At least one member of the IRB present at the IRB meeting and involved in the review will be a prisoner or a prisoner representative. The prisoner representative will have a close working knowledge, understanding, and appreciation of prison conditions from the perspective of the prisoner.
 - 1.** The prisoner representative must be a voting member of the IRB. The prisoner representative may be listed as an alternative member who becomes a voting member when needed.
 - 2.** The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner representative will receive all review materials pertaining to the research (as will the rest of the committee).
 - 3.** The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.
 - a)** The prisoner representative may attend the meeting by phone, videoconference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.
 - 4.** The prisoner representative must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 5.003

Title: Prisoners

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

- C. The IRB will notify OHRP of any change in the IRB roster by the addition or change of a prisoner representative, as required by Health and Human Services regulations at 45 CFR §46.103(b) (3). The IRB will be aware of the impact of roster changes on quorum requirements under Health and Human Services regulations at 45 CFR §46.108(b).
- D. The IRB is aware that the special composition requirement for research involving prisoners involves not only the initial review of the protocol, but also continuing review, protocol/consent amendments, review of reports of unanticipated problems involving risks to participants, and all other IRB matters pertaining to the protocol.

2.8 IRB Findings

The IRB will follow all pertinent federal regulations pertaining to human participant research, as well as make seven additional findings for research involving prisoners regardless of funding source:

- A. The research represents one of the categories permissible under Health and Human Services regulations pertaining to research involving prisoners.
- B. Any possible benefits to the prisoner through his/her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his/her ability to weigh the risks of the research against the value of such advantages in the limited-choice environment of the prison is impaired.
- C. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
- D. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control participants will be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
- E. The information is presented in language which is understandable to the participant population.



- F. Adequate assurance exists that parole boards will not take into account a prisoner's participation in research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.

2.9 If the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner's sentences and for informing participants of this fact. Documentation of IRB Findings Per federal regulations, the IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart C, the IRB activities include making the specific findings required under Health and Human Services regulations along with protocol-specific findings justifying those determinations. OHRP accepts documentation of protocol-specific information justifying each IRB finding required under 45 CFR §46.305(a) to be one way of adequately documenting the IRB activities required under Subpart C. The IRB will follow the aforementioned OHRP guidance.

2.10 Health and Human Services Funded Research - Notification to OHRP

- A. The IRB is responsible for providing certification to OHRP that the IRB has made the seven findings applicable to Health and Human Services funded research involving prisoners. The IRB will send OHRP a certification letter to this effect, which includes:
1. The name and address of the Institution
 2. Identification of the research protocol and relevant Health and Human Services grant application or protocol.
 3. A copy of all paperwork necessary for IRB initial review (IRB-approved protocol, relevant Health and Human Services grant application or proposal, IRB application, consent(s), etc.).
 4. Verification of the presence of a prisoner representative during consideration of the study.
 5. Verification of the seven required findings (listed above).
 6. Determination that the research meets one of the above categories of research permissible by federal regulations.
- B. Prisoner research certification letters should be mailed to the OHRP Prisoner Research Contact person in the Office for Human Research Protections at the Department of Health and Human Services.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 5.003

Title: Prisoners

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

2.11 Department of Defense regulated research involving prisoners

- A. Research involving prisoners of war is prohibited.
- B. The IRB must be aware of the definition of “prisoner of war” for the Department of Defense component granting the addendum.

2.12 Documentation of IRB findings under Subpart C

The IRB will fully document compliance with Subpart C in the minutes of the IRB meeting by documenting the required determinations and protocol-specific findings justifying those determinations. The IRB Approval letter will also reflect compliance with Subpart C if applicable.



1.0 Purpose

The purpose of this SOP is to describe the procedures for research involving children.

2.1 Policy

It is the policy of the IRB that the board will review all exempt and non-exempt research proposals involving participation of children in accordance with Health and Human Services regulations at 45 CFR §46 Subpart D and applicable state law. The IRB will classify the research in accordance with Subpart D and document how and why the proposal meets the requirements.

2.2 Definitions

- A.** Age of majority is defined, according to the Annotated Code of Maryland, Article 1, Section 24(a). It states that “...a person eighteen years of age or more is an adult for all purposes whatsoever and has the same legal capacity, rights, powers, privileges, duties, liabilities, and responsibilities ... and the ‘age of majority’ is hereby declared to be eighteen years.”

HRPP staff, in consultation with the IRB chair, will determine which individuals meet the DHHS definition of “children” in the cases that the research is conducted outside Maryland.

- B.** Assent is defined as a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- C.** Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Informed consent shall mean consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice in the locality or in similar localities. Failure to



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 5.004

Title: Children

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: October 1, 2020

obtain informed consent shall include failure to obtain any express or implied consent for any operation, treatment, or procedure in a case in which a reasonably prudent health care provider in the community or similar communities would have obtained an express or implied consent for such operation, treatment, or procedure under similar circumstances.

When the research is conducted in Maryland: In DHHS regulations “children” are persons who have not attained the legal age to consent to treatments or procedures involved in some research, under the applicable law of the jurisdiction in which the research will be conducted. In Maryland, individuals under the age of 18 years with the exceptions noted below are considered to be “children” as defined by DHHS regulations because they have not attained the legal age to consent to treatments or procedures involved in some research and the additional protections of Subpart D are required. The exceptions to this rule are the following individuals who are able to consent to treatments or procedures involved in the research, so that they do not meet the DHHS definition of “children” and the additional protections if Subpart D are not required:

1. Emancipated minors.
2. Individuals of any age where the research procedures are limited to: use of contraceptives; treatment for venereal disease; treatment for drug abuse.

NOTE: For research conducted in jurisdictions other than Maryland, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The General Counsel for the University’s Office will provide assistance with regard to the laws in other jurisdictions.

- D. Commensurate** is defined as the requirement that children and/or their guardians are familiar with procedures that are reasonably similar in nature and risk proportionally to those the child has experienced, or is expected to



experience, and not restricted to specific situations the child has experienced or will likely experience in the future.

- E. Disorder or condition** is defined as a specific (or set of specific) physical, psychological, neuro developmental, or social characteristic(s) that an established body of scientific evidence or clinical knowledge has shown to negatively affect children's health and wellbeing or to increase their risk of developing a health problem in the future.
- F. Dissent** is defined as a child's decision to decline participation in research.
- G. Emancipated minor** is defined as a legal status conferred upon persons who have not yet attained the age of legal competency as defined by Maryland state law, but who are entitled to treatment as if they had. Some minors do not meet the DHHS definition of "children," such as in Maryland individuals under 18 years of age who are legally emancipated or who are otherwise able to consent to the procedures involved in research. Federal regulations require that to take part in research the legally effective consent must be obtained from such individuals or their legally authorized representative.
- Emancipated minor** shall mean a person under eighteen years of age who is married or in the military, and it shall also mean a person under eighteen years of age who resides apart from his or her parents; is not under the care, custody, control, or supervision of his or her parents; and who receives no financial support or services from his or her parents and is responsible for securing his or her own support. The emancipation of a child is a question of fact, to be determined by the peculiar facts and circumstances of each case, and may be proved by circumstantial evidence, by an express agreement, or implied from the conduct of the parties. Emancipation may be terminated by a change of circumstances.
- H. Guardian:** A guardian is defined as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care (45 CFR 46.402 (e)).



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 5.004

Title: Children

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

NOTE: For research conducted in jurisdictions other than Maryland, the research must comply with the laws regarding legally authorized representative in all relevant jurisdictions. The General Counsel of the University's Office will provide assistance to the investigator with regard to the laws in other jurisdictions.

- I. **Legally authorized representative:** Legally authorized representative is defined as an individual or judicial body authorized under applicable law to give informed consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (21 CFR 50.3 (m)). IRBs and clinical investigators should familiarize themselves with applicable local statutes and regulations pertaining to the definition of a legally authorized representative.

Parents and guardians meet the DHHS and Maryland definitions of a legally authorized representative. For persons with a "Power of Attorney", whether the power of attorney in a given case will convey the authority to consent to participation on behalf of the principal in research depends on the specific language used in the durable power of attorney document.

The term "legally authorized representative" is not defined in the Maryland statutes. Under Maryland law there are essentially two different circumstances under which a person can act as a guardian or "legally authorized representative" for another adult. The investigator makes the decision about whether a person is a legally authorized representative, i.e., falls under the above. In general, researchers at UMCP conducting research in Maryland and enrolling adults unable to consent can get permission for those individuals to participate in research from:

1. an individual's court appointed guardian which includes de facto health care Power of Attorney; or
2. a person having "Power of Attorney" for another person.

NOTE: For research conducted in jurisdictions other than Maryland, the research must comply with the laws regarding legally authorized representative in all relevant jurisdictions. The General Counsel of the University's Office will provide assistance to the investigator with regard to the laws in other jurisdictions.



- J. Minimal risk** is defined as the risks that normal, average, healthy children encounter while living in safe environments or the risks associated with routine physical or psychological examinations or tests. The determination of minimal risk should take into account that: **1)** children face differing risks at different ages, **2)** risks associated with repetitive tests may increase, and **3)** special/unique characteristics may make a certain population more vulnerable than average children (e.g., hemophilia). The risks associated with routine examinations or tests are equivalent to a routine well-child examination.
- K. Minor increase over minimal risk** is defined as the determination whether the research procedures or interventions present a minor increase over minimal risk. The IRB will consider the following five criteria: magnitude, probability, duration, cumulative characteristics, and irreversibility of risk to the child.
- L. Parent** is defined as a child's biological or adoptive parent. The father and mother are the natural guardians of their minor children and are duly entitled to their custody and to direct their education, being themselves competent to transact their own business and not otherwise unsuitable. If either dies or is disqualified for action, or has abandoned his or her family, the guardianship devolves upon the other.

Therefore, in Maryland a father or mother of a child under the age of nineteen can act as a "legally authorized representative" of that child so long as their rights have not been terminated by law and so long as their minor child is not married or in the armed forces. For research conducted in jurisdictions other than Maryland, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The Office of General Counsel will provide assistance with regard to the laws in other jurisdictions.

- M. Permission** is defined as the agreement of parent(s) or guardian(s) to the participation of his/her (their) child or ward in research.
- N. Vital importance** is defined as the research is essential for the scientific understanding or evaluation of procedures to alleviate the disorder or condition and perceived as essential to the understanding or amelioration of the child's disorder by practitioners and family stakeholders.



2.3 Categories of Research

Health and Human Services regulations specify that research involving children must be approvable under one or more of the following four (4) categories:

- A. **Research not involving greater than minimal risk (e.g. most educational studies, studies in which behavior is not manipulated) (45 CFR §46.404)**
 1. The potential risks must be outweighed, or balanced, by the potential benefits to the participants and/or society.
 2. Adequate provisions must be made for soliciting assent of the children and permission of the parent(s) or guardian(s).

- B. **Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual participants (45 CFR §46.405)**
 1. The risk is justified by the anticipated benefit to the participants.
 2. The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
 3. Adequate provisions are made for soliciting the assent of the children and permission of their parent(s) or guardian(s).

- C. **Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition (45 CFR §46.406).**
 1. The risk represents a minor increase over minimal risk.
 2. The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
 3. The intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition, which is of vital importance for the understanding or amelioration of disorder, or condition.



4. Adequate provisions are made for soliciting assent of the children and permission of their parent(s) or guardian(s).

- D. **Research, not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR §46.407).**

The IRB will submit this category of research to Health and Human Services for approval, if the research is funded by Health and Human Services. If the research is not Health and Human Services-funded, the IRB will, at the board's discretion, convene an equivalent expert review panel.

2.4 Process of Consent/Assent

- A. In accordance with 45 CFR 46.408(b) the IRB must determine that adequate provisions have been made for soliciting the permission of each child's parent or guardian.

In general, if an individual is not a parent, they can permit a child to take part in research only if that individual is legally authorized to make health care decisions for the child. Under federal law this is the case even for social and behavioral research. Before obtaining permission from an individual who is not a parent, make sure that the person is legally authorized to make health care decisions for the child. If needed, ask for written documentation of the individual's authority to make health care decisions on behalf of the child. If the person has such authorization, the individual can permit the child to take part in the research. If the person does not have such authorization, the individual cannot permit the child to take part in the research.

Parents or guardians must be provided with the basic elements of consent as stated in 45 CFR 46.116(a) (1-8) and any additional elements the IRB deems necessary.

The IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 or 45 CFR 46.405. The IRB's determination of whether consent must be obtained from one or both parents will be documented in the consent checklist when a protocol receives expedited review, and in meeting minutes when reviewed by the convened committee.



Consent from both parents is required for research to be conducted under 45 CFR 46.406 and 45 CFR 46.407 unless:

1. One parent is deceased, unknown, incompetent, or not reasonably available; or
2. When only one parent has legal responsibility for the care and custody of the child.

B. Consent of a Mature Minor

A minor may, with IRB approval, legally consent on his/her own behalf when he/she do not meet the DHHS definition of “child”. In Maryland, if a participant under the age of 18 is legally declared emancipated, he/she may consent to participate in research because the individual no longer meets the DHHS definition of a child and therefore, Subpart D does not apply.

C. Assent of Children

In addition to the obtainment of parental/legal guardian consent (permission), the investigator must also solicit assent of minor participants age 7 years or older, unless the participants displays intellectual or emotional development below that of the average 7-year- old child. Obtainment of assent shows respect for a child’s developing autonomy. In most circumstances (non-therapeutic research), a child’s deliberate objection should be regarded as a veto to his/her involvement in the research.

D. Purpose of Assent

Assent serves to provide information to the child and to allow the child to dissent. With these purposes in mind, the following points should be considered when writing the Youth or Child Assent Form.

1. In deciding whether to seek assent, the minor’s age is an important criterion, but intellectual and emotional development also need be considered. The child must be able to identify the benefits and risks of the research, and to be able to reason about the consequences of participation as well as a typical 7 year old;
2. When there is uncertainty as to whether assent should be sought from the child or adolescent, an independent psychological examiner should be employed to help evaluate the minor’s decision-making capacities;



3. A valuable function of seeking assent from the minor is to provide information that the minor and his/her parents may use in their decisions concerning the research; and
4. In seeking assent, undue advantage should not be taken of the child's developmental limitations related to his/her voluntariness (acquiescence to authority figures and any lack of ability to express his/her rights).

E. Dissent of Children

Dissent from participation or withdrawal from research is always to be honored unless the protocol affords access to a therapeutic intervention that is not otherwise available. In that case, parental consent for therapeutic intervention may override a child's dissent. However that information must be provided to the child prior to the intervention procedure.

F. Waiver of Assent

Parents or guardians may, with IRB approval, override a young child's objections to interventions that hold the prospect of direct benefit to the child in accordance with 45 CFR §46.408(a). Assent may also be waived by the IRB under 45 CFR §46.116(d).

G. Situations Where Minors Are Not Children

Under the following circumstances, minors are not considered "children" and can consent for themselves:

1. If the research only involves a treatment for, which a minor's consent is permissible under applicable law (e.g., use of contraceptives, treatment for venereal disease or substance use).
2. If a participant under the age of 18 is legally declared emancipated, he/she may consent to participate in research.

H. Waiver of Parental Permission

Situations may be encountered where, with appropriate scientific rationale and justification, the IRB may approve a waiver of the requirements for parental consent.



1. The research meets the criteria for waiver of informed consent in 46.116(d):
 - a) The research involves no more than minimal risk to the subjects;
 - b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c) The research could not practicably be carried out without the waiver or alternation; and
 - d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

I. Wards

Health and Human Services regulations at 45 CFR §46.408 set specific requirements for children who have been declared wards of the state or any other agency, institution, or entity.

Wards can participate in research approved under §46.406 or § 46.407 if:

1. The research is related to their status as a ward.
2. The research is conducted in schools, camps, hospitals, institutions, or similar settings where the majority of children involved in research are not wards.
3. The IRB will require appointment of an advocate for each child who is a ward:
 - a) The advocate serves in addition to any other individual acting on behalf of the child as a guardian or in the absence of the parent(s).
 - b) The advocate may represent more than one child.
 - c) The advocate must have the background and experience to act in the best interest of the child for the duration of the child's participation in research.



- d) The advocate must not be associated in any way with the research, the investigator(s), or the guardian organization. The federal regulations do not specifically exclude IRB members from serving as a child advocate if the other conditions are met.

J. Re-consent of participants reaching the age of majority

1. All minor participants actively participating in an IRB-approved study must be consented using the adult IRB-approved informed consent document at the first visit after reaching the legal age of majority. If the minor participated in a study that is completed, except for data analysis, re-consent is not required.
2. If, upon reaching the age of majority, the now adult participant is found decisionally impaired or is of diminished capacity, the participant remains vulnerable and the proxy/parental consent remains in effect. This must be documented in the study records and the IRB must be notified.
3. The now adult participant has the right to refuse to continue participation in the study. This is to be respected and undue pressure or coercion to continue may not be applied. While new data may not be collected on participants refusing participation, existing prior data collected under the assent/proxy consent process can be used.

2.5 Consent and Assent Documents

A. Parental/Guardian Consent Form

If the participant is under the age of 7 years, only a Parental/Guardian Consent Form is required. The Parental/Guardian Consent Form should include all relevant elements of informed consent as outlined previously and be written in a proxy consent style that indicates it is the parent, or legal representative, who is consenting to allow the minor to participate in the study. The standard statements must be modified for the Parent Consent form (e.g., all references to “you” must be changed to “your child”).



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 5.004

Title: Children

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

B. Youth Assent Form

If the participant is 13-18 years of age, a Youth Assent Form is required. The Youth Assent Form is based on the adult consent form, but should be revised to meet the cognitive and educational level of an average youth. The assent form must contain simple language written at the appropriate educational level of the youngest prospective participant in the youth age range. In some research projects, it may be necessary to utilize two assent forms written to accommodate participants at either end of the age range. The Youth Assent Form must contain all of the required elements of consent previously outlined in the IRB Guidelines except instructions about emergency care and rights of research participants, and should follow the general format of the adult consent form.

C. Child Assent Form

1. If the participant is under the age of 7 years, only a Parental/Guardian Consent Form is required. However, verbal assent should be obtained as appropriate.
2. If the participant is 7 through 12 years of age, a Child Assent Form is required. The Child Assent Form must be brief, without subheadings, and contain extremely simple language arranged in brief paragraphs. The assent form must contain the following elements: title of the research study; opportunity to ask questions; basis for participant selection; purpose of the study; explanation of procedures; potential risks/discomforts; potential benefits; statement concerning consultation with parents; freedom to withdraw; and confidentiality statement.

2.6 Documentation of IRB Findings

Per federal regulations, the IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart D, the IRB activities including making the specific findings required under Health and Human Services regulations along with protocol-specific findings justifying those determinations. OHRP accepts documentation of protocol-specific information justifying the IRB finding under Health and Human Services regulations at 45 CFR §46.404, §405, or §406. IRB actions will be documented in the approval letter.



UNIVERSITY OF
MARYLAND

Human Research Protections

Policies and Procedures

Research Compliance Office

Institutional Review Board

Policy #: 5.004

Title: Children

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

The IRB will fully document compliance with Subpart D in the minutes of the IRB meeting by documenting the required determinations and protocol-specific findings justifying those determinations. The IRB Approval letter will also reflect compliance with Subpart D if applicable.



1.0 Purpose

The purpose of this SOP is to describe additional protections for decisionally impaired participants.

2.1 Policy

It is the policy of the IRB that research involving decisionally impaired participants who cannot provide voluntary informed consent must include appropriate additional protections in accordance with the requirements of Health and Human Services regulations at 45 CFR §46.111(b).

2.2 Definitions

A. Decisionally Impaired Participant

A person that lacks the ability to reason, exhibit sound judgment and provide voluntary consent to participate in research. The impairment may fluctuate (e.g., mental disorders), decline with time (e.g., Alzheimer's), or result from health conditions (e.g., coma or other infirmity).

B. Legally Authorized Representative

The term "legally authorized representative" is not defined in the Maryland statutes. Under Maryland law there are essentially two different circumstances under which a person can act as a guardian or "legally authorized representative" for another adult. The investigator makes the decision about whether a person is a legally authorized representative, i.e., falls under the above. In general, researchers at UMCP conducting research in Maryland and enrolling adults unable to consent can get permission for those individuals to participate in research from:

1. an individual's court appointed guardian which includes de facto health care Power of Attorney; or
2. a person having "Power of Attorney" for another person.

C. Institutionally Authorized Surrogate

In the absence of a legally authorized representative as described in 2.1(B), no one can provide legally effective consent on behalf of a participant to the participant's participation in research. Under federal regulations



Institutionally Authorized Surrogates who do not meet the DHHS definition of Legally Authorized Representatives may not provide consent on behalf of another individual unless the IRB has waived the requirement for informed consent.

2.3 Acceptable Research

- A. A decisionally impaired participant may participate in research involving greater than minimal risk only if the research potentially offers an acceptable level of direct therapeutic benefit to that participant.
- B. A decisionally impaired participant may participate in research involving minimal or slightly above minimal risk without direct participant benefit if a Legally Authorized Representative is available and provides proxy consent.

2.4 Use of Proxy Consent

- A. If the prospective participant is decisionally impaired, the participant's Legally Authorized Representative must provide written proxy consent.
- B. If the prospective participant is decisionally impaired, but is capable of executing a Durable Power of Attorney, the prospective participant may grant authority to the holder of the Durable Power of Attorney to give written informed consent to participate in research on their behalf. The Durable Power of Attorney in this case is a Legally Authorized Representative.
 1. The Durable Power of Attorney may already be in effect or one may be appointed to grant proxy consent for research participation.
 2. The Durable Power of Attorney is to be used only with prior approval of the IRB.
 3. The Durable Power of Attorney cannot be used if the prospective participant has a Legally Authorized Representative.
 4. The prospective participant must understand the meaning of a Durable Power of Attorney and appoint someone of their choice.
 5. The person appointed as a Durable Power of Attorney must be willing to do so and understand the responsibilities involved.



Policy #: 5.005

Title: Decisionally Impaired Participants

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 30, 2020

6. Employees of UMCP are not eligible for appointment as holder of a Durable Power of Attorney for a prospective participant unless they are the spouse, adult child, parent, or relative of the prospective participant.
7. A nursing home (e.g., owner, part-owner, manager, administrator, or employee, as well as spouses of these individuals) providing residential care to a participant or a community based program is not eligible for appointment as holder of a Durable Power of Attorney for prospective participants.
8. Signed copies of the Durable Power of Attorney form should be maintained by the investigator.
9. The HRPP office must be contacted prior to appointing a Durable Power of Attorney.

- C. If the potential participant does not have a Legally Authorized Representative and is judged by the investigator to both lack the capacity to give consent and execute a Durable Power of Attorney, the research may only be conducted if the IRB waives the requirement for consent.

2.5 Proxy Consent Form

The Proxy Consent Form must include all required elements of the informed consent and be written in the proxy consent style that indicates that the Legally Authorized Representative is providing permission to allow the decisionally impaired participant to participate in the study.

2.6 Adult Assent Form

The Adult Assent Form is based on the adult consent form but should be written in simple language aimed at the appropriate cognitive level of the decisionally impaired participants to be enrolled in the study. The Adult Assent Form must contain all required elements of consent.

2.7 Application of Laws

IRB and/or investigators must apply State and local laws that reach beyond Federal laws relevant to research involving humans as participants. Examples of such laws are reporting of child abuse and educational privacy laws. University counsel is available



UNIVERSITY OF
MARYLAND

Human Research Protections

Policies and Procedures

Research Compliance Office

Institutional Review Board

Policy #: 5.005

Title: Decisionally Impaired Participants

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 30, 2020

for advice in all cases as needed and requested. UMCP HRPP staff and or members of the IRB have access at all times to university legal counsel for assistance in applying laws to other than federal law regarding research involving human participants.



1.0 Purpose

Students are in a subordinate position to faculty members and instructors; therefore, a potential for coercion or undue pressure exists when course credit is awarded for research participation. For this reason, recruitment of students in the laboratory or classroom requires additional safety considerations.

2.1 Project Requirements for Extra Credit Compensation

The following must be included in the IRB protocol submitted through IRBNet:

2.2 Class syllabus:

- A. Description of the proposed research activity along with the points allowed for extra credit must be submitted with the IRB protocol. It is recommended that the extra credit for research be worth no more than 2% of the class grade.
- B. Personal identifiers, such as names, initials, social security numbers, or institutional ID numbers (i.e. UID) should not be included in the research records in order to earn credit.
- C. Description of alternative non-research activities for credit.
 - 1. The alternative activity should be equivalent in time, energy, and effort to participating in the research activity. For example, if the research requires a half hour to participate, the alternative activity should take the same amount of time to complete.
 - 2. Alternative activities should not be graded. If the research participant receives the credit for participating regardless of the quality of their participation, the alternative should be assessed on a similar participated/did not participate differentiation.
 - 3. Alternate activities may include but are not limited to the following:
 - a. Attend a specific presentation on campus,
 - b. Write an article/video review,
 - c. Participation in alternative research studies

2.3 Recruitment procedures clearly addressing:

- A. The nature of the supervisory relationship between the investigator and the prospective participants (e.g., includes students in a class being taught by the investigator).
 - 1. If participants are being recruited from the investigator's laboratory or class, describe procedures used to avoid potential



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 5.006

Title: Students and Extra Credit

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 30, 2020

coercion. (e.g., use of a general bulletin board posting and not engage in one-on-one solicitation; use of an individual to obtain consent that does not have any supervisory or instructional role relative to the prospective participant).

- B. Reference to approved department subject pool projects, if applicable.

2.4 Exclusions and Considerations

- A. Students cannot earn extra credit for research activities completed by another person.
- B. Students who are required to perform research worker activities (i.e., recruiting subjects, conducting interviews) to obtain extra credit, must complete the required CITI Training prior to engaging in the research activities.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 6.001

Title: Certification of Review to Funding Agencies
Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Revised: September 30, 2020

1.0 Purpose

The purpose of this SOP is to describe the process of certification of review to funding agencies.

2.1 Policy

It is the policy of the IRB that certification of review will be sent to funding agencies in full accordance with regulations at Health and Human Services 45 CFR §46.

2.2 Grant Application with Human Participant Research

When an investigator submits either a grant application involving human participants to Office of Research Administration or receives notification from National Institutes of Health of a fundable score, the investigator must identify the IRB number, which will cover the human participants activities described in the grant application. If the title on the IRB protocol on file does not match the title of the project listed on the grant application, the investigator should submit to the IRB an Amendment with either of the following:

- A. Addition of a second title (the title on the grant application) to the IRB protocol, OR
- B. Substitution of the new title

The Office of Research Administration will confirm with the IRB Office that IRB Approval is in place and request the IRB approval number. The Office of Research Administration is required to ensure that IRB review and approval of the grant application's human participant activities has been obtained by the investigator prior to any human participant research activity.

It is acceptable for consent document(s) to have a lay title rather than scientific title. However, this should be documented for the record in the IRB application.

2.3 Commercially Sponsored Contracts

It is preferable that titles match between all documents (i.e., contract, consent document(s), and IRB application). The sponsor's protocol number may be included in the protocol title; however, the IRB discourages inclusion of sponsor names in project titles.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 7.001

Title: Quality Assurance

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 30, 2020

1.0 Purpose

The purpose of this SOP is to describe the Quality Assurance Program.

2.1 Policy

It is the policy of the IRB that quality assurance compliance reviews (spot and for-cause) will be conducted in accordance with regulations at Health and Human Services 45 CFR §46.

2.2 Quality Assurance Program

The Quality Assurance Program has been developed to reflect the vision, purpose, and mission of the Institution and the HRPP.

The Quality Assurance Program is designed to be proactive, non-punitive, and focused on education of investigators, staff, and students about ethical and regulatory responsibilities in the conduct of human participant research. The focus of the program will encompass the IRB review process and IRB documentation.

2.3 Goal of Compliance Reviews

- A. Demonstrate the commitment of the Human Research Protection Program to the safety, rights, and welfare of human research participants by verifying the implementation of approved research protocols.
- B. Conduct reviews that are designed to assist researchers and their staff by:
 1. Verifying compliance with approved research projects;
 2. Identifying areas in their research operations where there could be unrecognized potential for non-compliance with regulatory standards;
 3. Recommending best practices approaches to minimize risks for study participants.
- C. Identify standards of excellence and potential areas for improvement in order to enhance the quality of human research protections at the University of Maryland, College Park



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 7.001

Title: Quality Assurance

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 30, 2020

- D.** Design training materials and programs to identify and promote best practices approaches to the research community at the University of Maryland.

2.4 Elements of Compliance Reviews

- A.** Review of IRB project records to include:
- 1.** Verification that IRB project personnel list matches current personnel;
 - 2.** Confirm current Human Subject training certification for all key personnel;
 - 3.** Verify current Responsible Conduct of Research training (where required);
 - 4.** Assure compliance with IRB requirements for amendment/continuing reviews/reportable events/etc.
- B.** The compliance review will involve an on-site visit by an HRPP staff member. Onsite visits will be conducted using the following procedures:
- 1.** Prior notification of the visit;
 - 2.** Scheduling the visit time with the investigator;
 - 3.** Informing the investigator of the specific records (e.g. consent forms) or procedures (e.g., data storage and security) that could be reviewed during the visit.
- C.** The following information will be requested from the investigator, to be checked against currently approved protocol and IRBfiles:
- 1.** The current recruitment documents and procedures;
 - 2.** The consent procedures and consent/assent forms in use;
 - 3.** Storage of research documents and data;
 - 4.** List of personnel who have access to data;
 - 5.** Any unexpected and/or adverse events;
 - 6.** If appropriate, the amount and documentation procedures for research subject payments



2.5 Selection of Projects

- A. Research projects to be reviewed will be selected randomly from each level of review. For example, if twelve reviews are conducted in a calendar year at least four of the reviews will be full board protocols, four expedited, and four exempt. Investigators who have a positive compliance review in the prior year will be removed from the sampling frame for the following year.
- B. The HRPP staff will conduct at least 12 compliance reviews annually. If any systematic problems are identified, additional reviews may be conducted to ensure broad compliance. This might involve additional reviews of protocols associated with a specific investigator and/or research administrative unit.
- C. The IRB may request a spot or for-cause audit of an approved human subject research project.
- D. Investigators may request a compliance review.

2.6 Review Process

- A. Investigators will be notified in advance of the selection of their project for a compliance review.
- B. The initial review will be conducted on IRB project files by staff in the HRPP office and will be completed within one week of the investigator notification.
- C. Upon completion of the internal record review, investigators will be notified of any identified concerns (e.g., human subject training not up-to-date for key personnel) and will be asked to complete a form to provide responses to the topics identified in 2.3C. The investigator will have two weeks to respond to the questions and any concerns identified in the initial review. Investigators may request an extension of the time to respond.
- D. After review of the investigator responses, and verification against project records, a follow-up on-site visit will be scheduled. The investigator will be advised in writing and the procedure outlined in 2.3B will be followed.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 7.001

Title: Quality Assurance

Section: *IRB Membership & Standard Operating Procedures*

Date: December 5, 2017

Reviewed: September 30, 2020

- E. Upon completion of the review, the HRPP office will issue a report of findings from the compliance review. The outcome of this review will fall into one of four categories:
1. No issues
 2. No compliance issues, but best practices advice to better document/improve selected aspects of the research protocol
 3. Minor compliance issues, included required corrective actions
 4. Major compliance issues. Depending on the nature of the issues identified, this may require suspension of the research and reporting to the appropriate university and federal office.

2.7 Review of the HRPP Program

- A. The components of the HRPP program will be reviewed annually by members of the HRPP Program and via a feedback survey distributed among PI's. The following components will be reviewed:
1. Communication process
 2. Review process
 3. Review Timelines
 4. IRB Meetings
 5. Outreach Activities
 6. OHRP Regulations
- B. The annual evaluation of the program will allow for continuous improvements to be made throughout the course of the year. The following people may review the program
1. IRB Chairperson
 2. IRB Members
 3. HRPP Director
 4. HRPP Staff
- C. The results of the reviews will be shared with the IO prior to implementing any program changes.



1.0 Purpose

The purpose of this SOP is to describe requirements for research conducted by students.

2.1 Policy

It is the policy of the IRB that research conducted by students will adhere to the regulations set forth in 45 CFR §46 as well as the ethical standards contained in the Belmont Report.

2.2 Introduction

Student participation in the research process is a valuable learning experience. The IRB supports this academic endeavor and has developed a specific policy to guide students and their advisor(s).

2.3 Research, Clinical Practica and Class Projects

Research, clinical practica (usually in the form of course-related research or evaluation projects and/or directed studies) and class projects are designed to provide students an opportunity to practice various research methods such as interview, observation and survey techniques, measurement of behavior (e.g., reaction time, speech, problem solving) as well as data analysis. Typically such projects are quite limited in scope, are not considered systematic investigations designed to develop or contribute to generalizable knowledge, and are not undertaken with that goal in mind. For example, a student may interview a peer when the interview does not involve any sensitive, personal information.

Such projects should not put the participants at more than minimal risk, and the data must be recorded anonymously by the students (e.g., with no names, social security numbers, or any other codes that can be linked to a list of names). These projects are considered "classroom exercises", are not systematic investigations designed to develop or contribute to generalizable knowledge and are not subject to review by the IRB. They do not require review unless the student researcher is conducting research involving human participants (that is, the activity is a systematic investigation designed to develop or contribute to generalizable knowledge) and the student is interacting or intervening with living individuals to



obtain information about those individuals or collecting private identifiable information about living individuals. If the student anticipates publishing the results or presenting at a professional meeting, consultation with the IRB should be obtained prior to beginning the activity.

2.4 Research Projects (Directed or Independent)

Any research conducted by students, graduate or undergraduate that does not fall under the definition of a research or clinical practicum, which uses human beings as participants and, which is a systematic investigation designed to develop or contribute to generalizable knowledge, must be reviewed and approved by the IRB. This includes, but is not limited to, all independent undergraduate research projects and honors theses, masters' theses and dissertations that involve research with human participants.

Recognizing the time constraints imposed on projects that must begin and be completed within a single semester, the IRB will make every effort to work with instructors to process proposals promptly. However, instructors must plan for and allow adequate time for the review process (approximately a week to a month, depending on the particular human participant issues raised by the proposed research). It is very strongly urged that instructors and/or students submit proposals within the first three weeks of the semester for projects that must be completed during the current semester.

2.5 Faculty Advisor Responsibilities

Faculty advisors as well as student researchers must complete the required CITI Training (Biomedical Research Investigators or Social & Behavioral Investigators) course to receive IRB Approval to conduct research with human participants.

It is the responsibility of faculty advisors to guide and oversee the IRB application submission process when an undergraduate or graduate student is the Principal Investigator. For example, faculty advisors have the responsibility to assist students in preparing review materials for the IRB and to ensure that the research is conducted in accordance with UMCP's agreement with the federal government and with applicable UMCP policy.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 8.001

Title: Students as Researchers

Section: General Requirements and
Guidelines

Date: December 5, 2017

Reviewed: September 30, 2020

2.6 Potential Practicum Problems

Students engaged in the process of learning research techniques understandably want to focus on compelling or real-life issues. In the process of reviewing student research, however, the IRB has found topics and subjects that raise concerns for the well-being of the participants and students themselves. Projects collecting data about illegal activities, those which could cause emotional distress in the participants, those which would place the students at risk if confidentiality were breached, and those with children as participants, need to be constructed with special care.

While practica are not under the purview of the IRB, the staff of the IRB is available for consultation with students and for class presentations regarding issues of the protection of the rights and welfare of human participants. It is important to note that data collected as practica cannot at a later date normally be used for presentation at conferences, publications, or doctoral dissertations. However, if a retrospective data review would be conducted on this data intended for contribution to generalizable knowledge, an IRB Application must be submitted to the IRB for review and approval.

2.7 Activities Requiring IRB Review

“All research involving human participants must be reviewed and approved by the IRB” (HRPP Policy #[3.001](#)). This directive includes research conducted by students.

To determine if the activity meets the definition of research, the investigation must “be a systematic investigation designed to develop or contribute to generalizable knowledge”. If the results of the investigation will be, or has the potential to be, published or presented through oral presentations, abstracts, or posters outside of the campus of UMCP, the definition of research might be indicated. Accordingly, the research, if it involves human participants, is subject to IRB review.

However, if the results of the investigation will be limited to, publications, oral presentations, posters, or abstracts solely on the UMCP campus, and relatedly are not systematic investigations designed to develop or contribute to generalizable knowledge, IRB review might not be required.



In order to determine if a project meets the definition of human subject research, a Human Subject Research Determination Form can be completed and submitted through IRBNet. The IRB Office will provide an official memo to the PI if the project does not qualify as human subject research. If the project does qualify as human subject research, the PI will be instructed to complete and submit the necessary IRB application documents.

UMCP students enrolled in graduate programs are required to have IRB Approval for thesis or dissertation projects involving human participants.

2.8 IRB Application and Review

There is not a separate IRB review process for student research. The student researcher is expected to follow all current IRB policies and procedures for IRB initial approval, continuing review, change requests, and other protocol matters. All deadlines and time frames will remain the same as for other researchers falling under the jurisdiction of the IRB.

Key personnel for research conducted by students may include:

- A.** The student as PI. It is the student's responsibility to carry out all of the obligations of a PI.
- B.** The student's advisor as a Supervising Investigator. It is the responsibility of the advisor to supervise the student's research project and provide necessary advice concerning IRB requirements and applicable federal regulations. Faculty who assign or supervise research conducted by students or staff have an obligation to consider carefully whether those individuals are qualified to safeguard adequately the rights and welfare of participants and have been properly trained in human research protection.
- C.** Other applicable Supervising Investigators and/or participating personnel.

2.9 Training in the Protections of Human Participant Requirements

The IRB requires that all key study personnel involved in the conduct of human participant research be certified by completion of a web-based training program (CITI). All students conducting research requiring IRB review must complete CITI training prior to IRB approval of the research. This includes exempt research. (HRPP Policy #[3.010](#))



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 8.001

Title: Students as Researchers

Section: General Requirements and
Guidelines

Date: December 5, 2017

Reviewed: September 30, 2020

Students participating in classroom projects that do not require IRB review are not required to complete CITI training. However, some colleges, departments, and sections may adopt internal requirements for all students to complete CITI training.



1.0 Purpose

The purpose of this SOP is to describe the guidelines required when conducting epidemiological research.

2.1 Policy

It is the policy of the IRB that all epidemiological research will be performed in accordance with the regulations set forth in 45 CFR §46.

2.2 Introduction

Epidemiological research is defined as the collection and analysis of medically relevant data about individuals or groups to determine the causes, distribution, and control of diseases in populations.

Some epidemiological research requires access to sources of Protected Health Information (e.g., medical records, databases, disease registries, and hospital discharge records). As a result the greatest risk associated with this research is breach of confidentiality and privacy. While the HIPAA Privacy Rule is not intended to obstruct epidemiological research, the investigator must understand and follow specific rules in order to meet the HIPAA Privacy Rule regulations, if applicable, as well as minimize the risks.

2.3 Development of the Protocol

During the development of an epidemiological research protocol, the investigator must consider several questions and be prepared to justify the responses in the IRB Application. Consideration of these questions will aid the investigator in meeting the requirements of the Privacy Rule, Health and Human

Services regulations at 45 CFR §46, as well as all applicable IRB requirements:

- A. What is the purpose of the research and what data is required to achieve the purpose of the research?
- B. Will retrospective (already existing) or prospective (collected in the future) data be used in the study?
- C. Where will the data come from (e.g., medical record review, databases, registries or clinical interaction with participants)?
- D. Will the research involve banking of data for future use or for purposes that are



not integral to the current research?

- E. Does, or will, the collected data contain Protected Health Information or other information that can be directly, or indirectly, linked to a participant? If yes, why will the link to a participant be required and how long will the identifiers be retained?
- F. Does the investigator have ethical access to the data (e.g., through a treatment relationship with potential participants or through control of an existent database)?
- G. Does the research have the potential to collect data on the participant (e.g., proband) and other related individuals (e.g., family members) identified by the participant or through other means (e.g., surveys and questionnaires)?

2.4 Protected Health Information

A. Identifiers

The Privacy Rule states that only the minimum Protected Health Information necessary to achieve the research objective can be used. Where it has been determined that participant identifiers are crucial to the research, the investigator must list the identifiers to be used and provide justification for their use (HRPP Policy #[10.001](#) for a list of identifiers).

B. Limited Data Set

In cases where the investigator provides justification for a need to maintain subject links to the data, the use of a Limited Data Set should be considered (HRPP Policy #[10.002](#)).

To obtain a Limited Data Set the investigator must complete a Data Use Agreement. This will identify the investigator as the recipient of the Limited Data Set, how the data may be used and disclosed by the investigator and provide assurances that the data will be protected.

During consideration of the application, the IRB will determine if the use of the limited data set meets the HIPAA, if applicable, and Health and Human Services requirements for waiver of informed consent.



C. De-Identified Data Set

If the data has been de-identified, the IRB will consider one of two (2) review options:

1. The IRB may determine that this qualifies for exemption under Health and Human Services regulations at 45 CFR §46.101(b)(see HRPP policy # [4.001](#) for a listing of the research categories that qualify for exemption.)
2. The research is not considered human participant research, therefore it is not subject to Health and Human Services regulations at 45 CFR §46.

2.5 Informed Consent

Informed consent must be obtained from the participant, unless the IRB approves a waiver or alteration.

2.6 Waiver or Alterations of Informed Consent

While protection of patient privacy and confidentiality is the primary goal of the HIPAA regulations, it is understood that situations may arise where obtaining informed consent may be impractical (e.g., research conducted on existing databases or repositories where no contact information is available). In these cases, HIPAA and Health and Human Services regulations have provided for IRB waiver or alteration of informed consent, if approved by the full IRB. The following criteria must be met (HRPP Policy #[9.006](#)):

- A. The use or disclosure of Protected Health Information involves no more than minimal risk.
- B. An adequate plan to protect participant identifiers from improper use and disclosure must be presented to the IRB (e.g., data is coded or linked and the codes are stored separately).
- C. An adequate plan to destroy participant identifiers at the earliest opportunity must be presented to the IRB (unless there is a health or research justification for retaining the identifiers or required by law).
- D. Using the “reasonable person standard”, the alteration of waiver of informed consent will not adversely affect the rights and welfare of the individuals.
- E. The research cannot practicably be conducted without the waiver or alteration



of informed consent and justification is provided.

- F. The research cannot be conducted without access to and use of the Protected Health Information. The objectives and validity of the study must provide justification for the use of specific Protected Health Information.
- G. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

2.7 Participant Recruitment

All participant recruitment activities must be approved by the IRB (HRPP Policy # [3.011](#)).

IRB approval of the recruitment plan is particularly important in situations where the investigator requests that a participant identify family members (or other applicable individuals) that might qualify for the study. It is important to note that the investigator has ethical access only to the enrolled participant, not those individuals identified by the participant. The investigator, or specialist, may not directly contact the family members (or others) without permission of those individuals.

The IRB recommends where possible the following recruitment plan be utilized:

The participant may be asked if they have family members that might qualify for the study. Rather than request the names and contact information, the investigator should ask the participant to speak with family members about the project. The participant may be provided an IRB-approved informational brochure or letter to give to the family member. The brochure/letter should provide information on whom to contact for further information. Alternately, it would be appropriate to provide self-addressed stamped postcards to the participant to hand out to family members. Interested family members (or others) could indicate their interest by returning the card with names and contact numbers filled in. In both cases, contact would be initiated by individuals expressing an interest in the study.

2.8 Research Involving the Development of a Database

There are two separate activities to consider in the development of a database. Each is considered a separate research activity under the HIPAA regulations and will require



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 8.002

Title: Epidemiological Research Guidelines

Section: *General Requirements and Guidelines*

Date: December 5, 2017

Reviewed: September 30, 2020

IRB-approved authorization, unless the IRB grants a waiver or alteration to the informed consent requirement:

- A.** The use or disclosure of Protected Health Information for creating a research database or repository.
- B.** The use or disclosure of Protected Health Information in the database for a future research purpose.
- C. Creation of a Research Database or Repository**

During consideration of an IRB application to create a research database or repository, the IRB must consider:

 - 1.** Will the database maintain Protected Health Information? If yes, what is the investigator's justification?
 - 2.** Will HIPAA Authorization be required, or does the database meet the qualifications for waiver or alteration of informed consent? In most cases, if the database involves collection of data through direct intervention or interaction with the participant, the IRB will require HIPAA Authorization.
 - 3.** Has the investigator provided sufficient assurance that the Protected Health Information in the database will not be used or disclosed for future research without IRB approval prior to use?
- D. Future Research Using a Database**

Creation of a database for the purposes of research does not mean the database can be used for any future research without specific IRB approval of the proposed study. Therefore, use of a database for research not specifically approved by the IRB requires submission of an application and approval by the IRB prior to use for future research. At that time, informed consent requirements will be based on the Protected Health Information present in the database, prior informed consent of the subject to authorize the placement of Protected Health Information in the database, the purpose of the research, and prior IRB waiver or alteration of informed consent.

**1.0 Purpose**

The purpose of this SOP is to describe the guidelines required when conducting studies that include exercise.

2.1 Policy

It is the policy of the IRB that all exercise studies will be conducted in accordance with regulations at Health and Human Services 45 CFR §46.

2.2 Introduction

The American College of Sports Medicine published guidelines in 2000 for use in studies involving exercise testing and prescriptions. These guidelines have been recognized as setting national standards. The guidelines, adopted by the IRB for research protocols involving exercise, reflect the American College of Sports Medicine 2000 guidelines and requirements of 45 CFR §46. These guidelines are largely based upon the following criteria:

- A.** Intensity of exercise.
- B.** Age of participant.
- C.** Apparent health status of participant.
- D.** Apparent fitness/activity level of participant.

The aforementioned criteria, in turn, determine health screening, monitoring, physician oversight and the type of IRB review (e.g., expedited continuing vs. full board). The IRB reserves the right to rule in exception to the exercise guidelines if necessary.

2.3 Health Screening

Appropriate participant health screening is required prior to the initiation of any maximal or sub-maximal intensity exercise test or program. Physician approval is required for participants that are at higher risk. A questionnaire may be administered by qualified study personnel to participants that are at lower risk.

This questionnaire should be submitted with the IRB Application.



2.4 Maximal Exercise Procedures

A. Cardiovascular Endurance

Cardiovascular endurance exercise procedures that are higher in intensity than 90% of maximal heart rate or 85% of maximal oxygen uptake or heart rate reserve maximum are regarded as maximal exercise and are considered in the category, which requires review by the full IRB.

B. Muscular Strength/Endurance

Muscular strength/endurance exercise procedures using maximal (e.g., one-to-five) repetitions require full IRB approval regardless of participant health, activity level, and/or age.

Isokinetic exercise testing programs (e.g., Biodex) at slow movement speeds are considered in this category.

Scientific justification will be required to support the use of exercises that are considered high risk. These exercises include, but are not limited to:

1. Squat
2. Dead Lift
3. Clean and Jerk
4. Overhead Press
5. Any equivalent of the above

2.5 Moderate Exercise Procedures

A. Cardiovascular Endurance

Cardiovascular endurance exercise procedures that are lower in intensity than 90% of maximal heart rate or 85% of maximal oxygen uptake or heart rate reserve maximum are regarded moderate exercise and are considered in this category.

2.6 Other Exercise Procedures

Investigators intending to use exercise procedures not addressed in these guidelines should compare the proposed exercise to the most closely related category and classification. Attention should be given to the intensity of the exercise, the age of the participant, the apparent health status of the participant, and the apparent fitness/activity level of the participant. Finally, the appropriateness of the exercise should



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 8.003

Title: Exercise Research Guidelines

Section: *General Requirements and Guidelines*

Date: December 5, 2017

Reviewed: September 30, 2020

be considered in relation to these factors.



1.0 Purpose

The purpose of this SOP is to describe the guidelines for research conducted in foreign countries.

2.1 Policy

It is the policy of the IRB that all research in foreign countries will be conducted in accordance with the regulations at Health and Human Services 45 CFR §46. The IRB will review all human subject research being conducted in foreign countries regardless of the foreign institution's IRB or Ethics Committee approval system.

2.2 Non-federally funded research

Non-federally funded research that is conducted in a foreign country is subject to all of the IRB requirements except that certain IRB requirements can be waived in consideration of the culture and local customs of the country in which the research is conducted. Investigators who seek a waiver of any IRB requirements must provide appropriate justification to the IRB.

- A. Any justifications for waivers of IRB requirements based on claims of local practices or customs will be independently verified with the foreign institution and/or appropriate governmental agency.

2.3 Federally funded research

Federally funded research that is conducted in a foreign country is subject to all of the IRB requirements with exceptions granted in accordance with the federal (model) policy and OHRP guidance.

According to the model policy for the protection of human participants and OHRP requirements, when federally funded research takes place in foreign countries, a FWA must be filed. However, procedures normally followed in the foreign countries to protect human participants may differ from those set forth in the model policy. In these circumstances, a department, or agency head, must determine that the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in the model policy. If the procedures meet these criteria, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in the model policy.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 8.004

Title: Research Conducted in Foreign Countries

Section: *General Requirements and Guidelines*

Date: December 5, 2017

Reviewed: September 30, 2020

2.4 IRB Requirements

Research that includes collaboration with an international institution must provide assurance to the IRB that all of its activities related to human participant research, regardless of funding source, will be guided by the ethical principles in one of the following documents:

- A. Declaration of Helsinki (as adopted in 1996 or 2000).
- B. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- C. Other appropriate international ethical standards recognized by federal departments and agencies that have adopted the US Federal Policy for the Protection of Human Subjects. A copy of these standards must be provided by the institution.

In addition, the IRB requires confirmation of IRB approval (or equivalent) from the foreign site, a copy of the protocol, and a copy of the informed consent document.

2.5 Verification of International Research Standards

The IRB will maintain links to information resources that provide information on foreign country regulations on human subject research. The DHHS Office for Human Research Protection (OHRP) maintains the International Compilation of Human Research Protections. The Compilation lists the laws, regulations, and guidelines for over 50 foreign countries.

This Compilation is maintained in electronic format, with direct web links to each country's regulatory organizations, laws, and other resources that establish local standards. OHRP provides this Compilation to assist researchers and IRBs in verifying that research studies are complying with local laws and customs. The Compilation can be accessed on the OHRP website:

<https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>



1.0 Purpose

The purpose of this SOP is to describe the guidelines for community-based research.

2.1 Policy

It is the policy of the IRB that all community-based research will be conducted in accordance with the regulations at Health and Human Services 45 CFR §46.

2.2 Definition of Community-Based Research

Community-based research (CBR) is a research paradigm that attempts to make research a more inclusive and democratic process by fostering the development of partnerships between communities and academics to address community-relevant research priorities. The CBR paradigm emerged from research with autonomous indigenous communities, particularly American Indian tribes, but has expanded to a broader scope. Broadly, communities in this research domain represent population groups with social structures, common customs, and acknowledged leadership. These 'communities' may include nations, cultural groups, small indigenous communities and some neighborhood groups.

Some of the unique elements of CBR include: **1)** active engagement and shared decision-making of community members and academic researchers, **2)** involvement of community approval and representation in the research approval, design, and implementation, **3)** integration of community social action, social change, priorities with the scientific objectives of the academic researchers, and **4)** consideration and respect for the rights of the community in all aspects of the research.

2.3 Special Considerations

In CBR human protections are not just about individuals but the respect, beneficence, and justice for the community. As such, the IRB review process requires documentation of access and approval to conduct research in communities.

Most communities do not have the equivalent of an IRB, and even those with some formal ethics review process typically do not have an established FWA. As such, the UMCP IRB cannot use a formal collaboration agreement to address the dual processing of human subjects' protections at the community and university levels. Rather, we have established the following additional review guidelines for CBR:



- A. IRB Review of CBR adds the principle of “respect for communities” or “respect for cultures” as a criterion for assessing the proposed research.
- B. Written consent of the community must be obtained prior to the IRB approval of a CBR study.
- C. If the study is not approved by the community, individual informed consent may not be used as an alternative to gaining community approval.

2.4 Community-based research resources

There are a number of resources available to guide and aid university investigators in the design and implementation of CBR.

Guidance for investigators:

- A. An annotated listing of CBR articles, reports and websites was prepared by Community-Campus Partnerships for Health for the Robert Wood Johnson Clinical Scholars Program. <https://www.ccphealth.org/clinical-scholars/>
- B. CBR: Engaging Communities as Partners in Health Research
<https://www.ccphealth.org/clinical-scholars/>
- C. Agency for Health Care Research and Quality commissioned literature review on CBR approaches <https://archive.ahrq.gov/clinic/epcsums/cbprsum.htm>

Resources for the IRB:

- D. The IRB has access to investigators on campus who have expertise in conducting CBR and may be called upon by the IRB to provide expert consulting for specific community studies.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 9.001

Title: Required Elements for Informed Consent Documents

Section: *Informed Consent*

Date: December 5, 2017

Revised: October 1, 2020

1.0 Purpose

The purpose of this SOP is to describe the required elements for informed consent documents.

2.1 Policy

It is the policy of the IRB that the IRB shall ensure that informed consent is documented in accordance with and to the extent required by 45 CFR §46.116, unless documentation is waived by the IRB as provided in 45 CFR §46.109(c) and §46.117.

2.2 Introduction

The IRB shall require that information given to participants as part of informed consent is in accordance with Health and Human Services regulations at 45 CFR §46.116. The IRB may require that information, in addition to that required by regulations, be given to participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of participants in accordance with 45 CFR 46.§109(b). The IRB has authority to observe or have a third party observe the consent process and/or the conduct of research 45 CFR §46.109(g). Guidelines through the use of a template are available to assist all investigators to meet requirements of the federal regulations and IRB (<https://research.umd.edu/irbforms#consentform>).

2.3 Investigator Responsibilities

The investigator has a legal and ethical obligation to ensure that the prospective research participant has sufficient knowledge and comprehension of the elements of informed consent, meaning that the prospective research participant must be able to make an informed decision whether or not to participate in research. Obtaining informed consent should be seen as a communication process of explanation and not as an act of signing a form. As part of the process of obtaining informed consent, each element of consent should be explained carefully and simply to the prospective participant. In addition, the investigator should assess periodically the prospective participant's comprehension by asking appropriate questions. Ultimately, the investigator bears full responsibility for obtaining valid informed consent from the participant.

Investigators should be sensitive to the possible needs of an interpreter or translator for participants who do not speak English as a first language or who are hearing impaired.



2.4 Mail/Telephone Surveys

Mailed surveys that are completely anonymous can meet the informed consent requirement in one of two ways: **a)** they can be sent out with an accompanying cover letter and an informed consent form, or **b)** they can be sent out with an accompanying informed consent form but written in a cover letter format.

If the second option is chosen, the return of the survey implies consent, which can be approved if the IRB grants an exemption determination or waives the requirement for documentation of the consent process. The letter would have to include notification of use of data, assurance of confidentiality, and phone numbers to contact in case of questions about participant's rights.

Some anonymous telephone interviews with adults can be handled in a similar way. It is preferred for the participant to receive a copy of the informed consent letter or form before the interview; however, in situations when that is not possible, information typically given on an informed consent form (notification of use of the data, assurance of confidentiality, phone numbers to contact in case of questions, etc.) can be included in an oral script that is read to participants to obtain oral consent. Oral scripts must be submitted to the IRB for review and approval before the study is conducted.

2.5 Required Elements for Informed Consent Documents

The following are the required elements that must be present in all consent documents.

The consent form must be:

- A.** Approved by the IRB and include the elements of informed consent required by 45 CFR §46.116 and 46.116(b)(1);
- B.** Signed by the participant or the participant's legally authorized representative [45 CFR §46.117(a)]; unless the IRB has waived the requirement for document of the consent process in, which case a cover letter may be used as an informed consent document; and
- C.** A copy must be given to the participant or legally authorized representative [45 CFR §46.117(a)].



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 9.001

Title: Required Elements for Informed Consent Documents

Section: *Informed Consent*

Date: December 5, 2017

Revised: October 1, 2020

The agreement, written or oral, entered into by the participant, may not include language through which the participant is made to waive, or to appear to waive, any legal rights, or to release the investigator, the sponsor, UMCP, or its agents from liability for negligence.

Informed consent should be appropriate to the research and participant population being studied.

D. Informed consent shall include the following elements:

1. A statement that the study involves research [45 CFR §46.116(b)(1)];
2. An explanation of the purposes of the research [45 CFR §46.116(b)(1)];
3. The expected duration of the participant's participation in the research [45 CFR §46.116(b)(1)];
4. A description of the procedures to be followed [45 CFR §46.116(b)(1)];
5. Identification of any procedures, which are experimental [45 CFR §46.116(b)(1)];
6. A description of any reasonably foreseeable risks or discomforts to the participants [45 CFR §46.116(b)(2)];
7. A description of any benefits to the participant or to others which may reasonably be expected from the research [45 CFR §46.116(b)(3)];
8. A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the participant [45 CFR §46.116(b)(4)];
9. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained [45 CFR §46.116(b)(5)];



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 9.001

Title: Required Elements for Informed Consent Documents

Section: *Informed Consent*

Date: December 5, 2017

Revised: October 1, 2020

10. For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs; whether any medical treatments are available if injury occurs; and, if so, what they consist of, or where further information can be obtained [45 CFR §46.116(b)(6)];
11. An explanation of whom to contact for answers to pertinent questions about the research and who to contact in the event of a research related injury to the participant. [45 CFR §46.116(b)(7)]. A contact phone number for the PI and the Supervising Investigator must be provided;
12. A statement of who to contact concerning questions about research participants rights, for example, “If you have questions about your rights as a research participant or wish to report a research-related injury, please contact the University of Maryland College Park Institutional Review Board Office at (301) 405-0678 or irb@umd.edu.”
13. A statement that participation is voluntary that refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled: for example “Participation in this study is voluntary. You can refuse to participate or withdraw at any time without harming your relationship with the researchers or the University of Maryland College Park, (include any other agency/institution you are working with), or in any other way receive a penalty or loss of benefits to which you are otherwise entitled.” [45 CFR §46.116(b) (8)].
14. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 9.001

Title: Required Elements for Informed Consent Documents

Section: *Informed Consent*

Date: December 5, 2017

Revised: October 1, 2020

informed consent from the subject or the legally authorized representative, if this might be a possibility; or

- b) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

15. If appropriate to the research, indicate whether the informed consent process provides the following 9 additional elements of information 45 §CFR 46.116(c):

- a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
- b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.
- c) Any additional costs to the subject that may result from participation in the research.
- d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- e) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.
- f) The approximate number of subjects involved in the research at the institution and nationally or internationally.

The IRB requires that information in addition to that required by Health and Human Services 45 CFR §46 be given to research participants when in its judgment the information would



meaningfully add to the protection of the rights and welfare of participants (Health and Human Services 45 CFR 109):

- i) The age of participants (under 18 require parental informed consent in Maryland except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research)
- ii) Where research takes place
- iii) When individuals with decisional impairments are potential research participants, the IRB may require the investigator to use techniques that would confirm that individuals did understand the consent process
- iv) A statement about why the participant was selected
- v) The IRB may require the consent process be monitored or observed when individuals with decisional impairments are involved
- vi) The IRB may require waiting periods prior to consenting
- vii) The IRB may require an advocate or ombudsman oversee the consent process for individuals with decisional impairments
- viii) The IRB may require procedural changes or additional protections for individuals with decisional impairments
- ix) A statement that if the participant was or became pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which were currently unforeseeable
- x) Procedures for the orderly termination of participation by the participant



- g)** A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- h)** A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- i)** For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

2.6 Documentation of Consent Process

The consent process must be appropriately documented in accordance with Health and Human Services regulations at 45 CFR §46.117. (HRPP Policy #[9.002](#)):

- A.** The participant must initial the bottom of each page of the consent, or the consent form should say page of__and formally provide their full signature, and date, at the end of the consent
- B.** The investigator's name and phone number must be listed at the end of the consent form

2.7 Observation of the Consent Process

- A.** The IRB can observe the consent process where it determines that such observation will meaningfully contribute to the reduction of risk to the research participant. For example, situations with vulnerable populations where observation of the consent might minimize coercion or undue influence, or situations involving non-compliance with the consent process.
- B.** If the IRB decides that the consent should be observed, the investigator would be



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 9.001

Title: Required Elements for Informed Consent Documents

Section: *Informed Consent*

Date: December 5, 2017

Revised: October 1, 2020

notified before such observation. The PI will be consulted collegially so that appropriate arrangements can be made for the observation to take place in a manner that is as unobtrusive as possible. HRPP staff would conduct the observation.

**1.0 Purpose**

The purpose of this SOP is to describe development of the informed consent document.

2.1 Policy

It is the policy of the IRB that the informed consent document will be developed in accordance with regulations at Health and Human Services 45 CFR §46.

2.2 Specific Layout Instructions

All consent/assent documents should be submitted suitable for reproduction and easy readability by potential participants.

Lines requiring the participant, witness, or PI signatures should not be placed on a separate page without the presence of any of the preceding language required in that section of the informed consent.

2.3 Identification of Type of Consent and Assent

To easily identify the type of consent/assent document, one of the following labels should be placed at the top of the first page:

- A. Adult Consent:** Utilized when enrolling competent adults (in Maryland defined as individuals 18 years of age or older and individuals under 18 years of age who are legally emancipated or who are otherwise able to consent to the procedures involved in the research).
- B. Parent or Legal Guardian Consent:** Utilized when enrolling children (in Maryland defined as individuals under 18 years of age except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research) in a research study.
 - 1. **Youth Assent:** Written assent to be used for children aged 13-17 years. A separate consent form should be used to obtain youth consent. However, in certain circumstances, it may be combined with the Adult Consent with additional signature lines added for the minor to sign.
 - 2. **Child Assent:** Verbal assent to be used for children aged 7-12 years.



3. **Child Assent:** Under age 7, a reasonable conversation should occur with the child and researcher about the research activities and their right to not participate.

C Proxy, Legally Authorized Representative, or Durable Power of Attorney Consent: Utilized when enrolling decisionally impaired adults.

1. **Adult Assent:** Used when enrolling decisionally impaired adults.

D. Screening Consent: Used to obtain participant consent to allow study- related screening tests for potential enrollment in a study. Full study consent will follow.

E. Addendum Consent: Commonly used to obtain additional consent from participants for auxiliary studies (e.g., tissue banking). Also may be used to inform currently enrolled participants of new information pertaining to the research.

2.4 Identification of Study Personnel

The PIs and Supervising Investigators, if any, listed in the IRB Application must be listed on the last page of the informed consent/assent document in accordance with Health and Human Services regulations at 45 CFR §46.111(a) (4) and §46.116(a) (7).

The following subheadings must be used (as appropriate):

- A.** Principal Investigator
- B.** Supervising Investigators (Faculty Advisor)

A contact phone number for the PI and the Supervising Investigator must be provided.

2.5 General Style of Consent Documents

The informed consent form should be written in the second person throughout (e.g., you are invited to participate; you will be assigned, etc.). When combined with conditional language and the invitation to participate, utilization of the second person communicates that the investigator believes there is a choice to be made by the prospective participant. Utilization of the first person may be interpreted as presumption of participant consent before consent has been legally obtained.



2.6 Parental, Legal Guardian, Proxy, and Durable Power of Attorney Consent Documents

Proxy consent documents should reflect that it is the minor, or other vulnerable participant, who is the participant in the study. The individual giving consent (parent or legally authorized representative) is providing permission to allow the participant to participate in the study.

2.7 Adult, Youth, and Child Assent Documents

Assent documents should reflect the age, maturity and cognitive ability of the decisionally impaired adults, youth, and children that will be the participants of the trial.

For further information about:

- A. Parental/legal guardian consent and youth/child assent: see HRPP Policy #[9.002](#).
- B. Proxy/DP consent and adult assent: see HRPP Policy #[9.002](#).

2.8 Readability

The consent form must be written in simple enough language so that it is readily understood by the least educated of the participants to be involved. Generally, the level of language in the adult consent document should be an eighth grade standard. Youth and child assent documents should be written in an age- appropriate style.

Medical and scientific terms should be avoided where possible. If medical jargon is used the lay terms should be used first and then the medical term included in parentheses.

Common units of measure should be used appropriate to the procedure or content.

It is recommended that the language consist of short, concise sentences arranged in relatively short simple paragraphs. Headers should be used to separate sections of the document for easier reading, particularly when describing what will happen during the study. Generally, abbreviations should not be used in the consent document that is, all words should be spelled out. The IRB may approve limited use of abbreviations where appropriate, as long as the acronym is spelled out the first time it is used.

2.9 Length

There are no restrictions on the length of the informed consent/assent documents. The



informed consent form should be lengthy enough to explain the elements of consent adequately, but not so lengthy or detailed as to lose the attention of the participant or to cause confusion.

2.10 Format

- A. Exempt Research:** If the research is exempt, but requires written informed consent (e.g., an educational study requiring parental consent), a narrative consent form may be used. In the narrative consent form, all necessary elements of consent should be present on the consent form, but the elements need not be identified by subheadings.
- B. Research Involving Minimal Risk or Greater:** If the research involves procedures, which are minimal risk or greater, the consent form template format must be used (HRPP Policy #[3.004](#) for a definition of minimal risk). The IRB has developed an informed consent document template that is designed to provide investigators guidance in the development of this form. The template and completion instructions are available on the HRPP website (<https://research.umd.edu/irbforms#consentform>).
- C. Waiver of Written Consent**
If consent will be waived and the PI intends to provide a consent document to the participants, an Information Sheet may be used. Typically, this will be the completed Consent Form template with the signature lines removed. Using the template will allow the PI to present the required consent elements to the participant.

2.11 Exculpatory Language

The consent document must not contain any exculpatory language through which the participant or the participant's representative is made to waive, or appear to waive, any of the participant's legal rights. Additionally the consent document must not release, or appear to release, the research investigator, the sponsor, the Institution, or its agents from liability for negligence.



1.0 Purpose

The purpose of this SOP is to describe the guidelines governing telephone consent.

2.1 Policy

It is the policy of the IRB that telephone consent will be gained in accordance with the regulations at Health and Human Services 45 CFR §46.

2.2 Introduction

Whenever possible, consent should be obtained in person by an authorized investigator. However, the IRB recognizes that an alternative informed consent process may, at times, be necessary for the safety of the participant. Therefore, under extenuating circumstances, when it is in the best interests of the participant, the IRB may approve an alternative informed consent process(es) via telephone. IRB approval of a verbal/telephone consent process for nonexempt research requires a waiver of the requirement for written documentation of consent. The consent discussion needs to include all required elements of consent disclosure unless the IRB approves a waiver or alteration of the consent process.

2.3 IRB Requirements for Use of a Verbal/Telephone Consent Process

The IRB will review the proposed method of consent based upon the nature of the study, the risk level, participant population needs and/or significance of the treatment related change. The proposed method of consent must be fully explained and justified in the IRB application (Section 7) or in the Description of Proposed Changes section of the Request for Change in Protocol Form.

The following describes IRB requirements for the use of telephone consent for re-consent for significant changes or disclosure of significant additional risks and re-consent for minor changes or disclosure of additional minor risks.

2.4 Verbal/Telephone Re-Consent for Significant Changes or Additional Risks

With appropriate scientific rationale and justification, the IRB may approve a telephone consent procedure to allow participant to be notified of significant new risks or changes.

- A. The consent document (revised consent form or addendum) must be provided to the participant for review prior to the telephone consent process. It is preferred that this be done by mail; however, email is acceptable when necessary. No research



interventions can be conducted until a signed copy (email or original) of the consent form has been received by the investigator. An extra copy must be provided for the participant to keep for their records.

- B.** A telephone call is scheduled. The minimum required participants in the consent process are: the participant; the investigator.
- C.** Each element of the consent document, which has been changed, must be explained to the participant, and the participant's comprehension must be assessed. The participant must be given the opportunity to ask questions. It may be necessary to extend the process over several days and include other individuals such as the participant's family members. If required, the participant must be instructed in the signing of the consent form and must return the original signed document to the investigator by mail. The participant must be re-consented in the presence of the investigator when he/she returns to research site for follow-up.
- D.** The alternative process of consent should be documented in the research record by indicating the reason for the alternative method used, and date.

2.5 Verbal/Telephone Re-Consent for Minor Changes or Additional Minor Risks

With appropriate justification, the IRB, under certain circumstances, may approve a telephone consent procedure for participants to receive notification of a minor new risk.

- A.** The consent document (revised consent form or addendum) must be provided to the participant for review prior to the telephone consent process. It is preferred that this be done by mail; however, email is acceptable when necessary. No research interventions can be conducted until a signed copy (email or original) of the consent form has been received by the investigator. An extra copy must be provided for the participant to keep for his/her records.
- B.** A telephone call is scheduled. Minimum required participants in the consent process are: the participant; the investigator.
- C.** Each element of the consent document, which has been changed, must be explained to the participant, and the participant's comprehension must be assessed. The participant must be given the opportunity to ask questions. If required, the



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 9.003

Title: Verbal/Telephone Consent

Section: *Informed Consent*

Date: December 5, 2017

Reviewed: September 30, 2020

participant must be instructed in the signing of the consent form and must return the original signed document to the investigator by mail. The alternative process of consent must be documented in the research record by indicating the reason for the alternative method used, date, time, and personnel involved in obtaining and documenting consent.

- D.** If a waiver of written consent was granted initially, the investigator may present the new information verbally over the telephone and make a note of the conversation in the research record. This must be clearly delineated during the Amendment submission to the IRB.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 9.004

Title: Re-Consent/Assent Process

Section: *Informed Consent*

Date: December 5, 2017

Reviewed: September 30, 2020

1.0 Purpose

The purpose of this standard operating procedure (SOP) is to describe the process of re-consent/assent of research participants.

2.0 Policy

It is the policy of the IRB that the process of re-consent/assent of research participants will be conducted in accordance with the regulations at Health and Human Services 45 CFR §46.

The initial informed consent/assent document(s) signed by the participant at enrollment remains in effect for the duration of the participant's participation in the study or until the IRB approves a change in the consent/assent document(s), which requires re-consent/assent of participants.

Informed consent/assent, however, is an ongoing process, not simply the document signed by the participant during enrollment in the research. In order to validate the voluntary nature of participation in research and exhibit respect for the individual, participants must be provided new information, which may affect their willingness to continue to participate in the research. Health and Human Services regulations at 45 CFR §46.116(b) (5), therefore, require investigators to inform participants of any important new information that is germane to the participant's willingness to continue participating in the study.

Each year, during the continuing review process, original consent/assent document(s) are submitted for review. Upon IRB re-approval of the study, if the project remains open to enrollment, the consent/assent documents are approved for use from that date until the expiration date or an amendment consent form is submitted for approval. The IRB does not require re-consent of previously enrolled participants at this time, unless the IRB approves a request for change during the continuing review process or identifies new information, which requires re-consent of the participants.

Commonly, minor information (e.g., changes in personnel or administrative changes in the consent document) is provided to participants through verbal exchanges between the investigator and participant, without undergoing a formal re-consent procedure. Minor information is unlikely to affect a participant's willingness to continue participation in a study. However, significant new information, which requires re-consent/assent of participants must occur through use of IRB-approved, revised consent/assent document(s) or an Amendment to the consent/assent form. For example, significant new information may include **1)** changes in the



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 9.004

Title: Re-Consent/Assent Process

Section: *Informed Consent*

Date: December 5, 2017

Reviewed: September 30, 2020

duration of the study, or **2)** major changes in the methods of the study.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 9.005

Title: Absence of Valid Consent

Section: *Informed Consent* **Date:**

December 5, 2017

Reviewed: September 30, 2020

1.0 Purpose

The purpose of this SOP is to describe the guidelines governing the re-consent and the use of data in the absence of valid consent.

2.0 Policy

It is the policy of the IRB that, in the absence of valid consent, re-consent and the use of data will adhere to the regulations at Health and Human Services 45 CFR §46.

The investigator has a legal and an ethical obligation to ensure that the prospective participant has sufficient knowledge and comprehension of the elements of informed consent prior to enrollment and during participation in research. This is accomplished through the initial and on-going process of informed consent.

If a participant enrolls and begins participation in a study without the presence of a valid informed consent document (e.g., the participant signed a wrong or outdated consent form), participant comprehension of the elements of informed consent and true informed decision making is called into question. The ethical principal of respect for persons demands that participants enter research voluntarily and with adequate information.

If a participant enrolls in a study without valid informed consent, the principal investigator must immediately notify the IRB Office and the participant and explain the situation. The PI should request that the participant re-consent to participate. If the participant agrees and the complete informed consent process is repeated, including signatures on the consent document and documentation of consent in the research record, data obtained during the period of invalid consent may be used with approval of the IRB.

If the participant refuses to consent, participation in the study must be halted immediately and the collected data cannot be used.



1.0 Purpose

The purpose of this SOP is to describe the situations in which the IRB may waive or alter the informed consent process and/or waive consent documentation.

2.0 Policy

It is the policy of the IRB that all requests for waiver or alteration of the informed consent process or consent documentation must undergo appropriate IRB review, and when waivers or alterations are granted, they are given based on Health and Human Services regulatory criteria at 45 CFR §46.111(a) (4) and (5), 45 CFR §46.116(e) and (f), 45 CFR §46.117(a) to (c).

2.1 Waiver of Documentation of Informed Consent

The Board, for some or all participants, may waive the requirement that the participant or the participant's representative sign a written consent document per 45 CFR §46.117(c) if it finds:

- A. That only the record linking the participant and the research would be a potential harm to the participant resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
- B. That the research presents no more than the minimal risk of harm to the participants and involves no procedure for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants a written statement regarding the research.

When the IRB considers waiving the requirement to obtain documentation of the consent process, the IRB should review a description of the information that will be provided to participants. When granting waivers of the requirement to obtain documentation of the consent process, the IRB should consider whether the investigator should provide participants with a written statement regarding the research.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 9.006

Title: Waiver or Alteration of Consent

Section: *Informed Consent*

Date: December 5, 2017

Revised: September 30, 2020

- C. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

2.1 Waiver or Alteration of Consent

The Board may waive the requirement for informed consent per 45 CFR §46.116(f)(3) (or allow an alteration of some or all of the elements of informed consent) only if the Board finds that each of the following four elements are met. This is different than waiving the requirement of documentation of informed consent.

- i. The research involves no more than minimal risk to participants; and
- ii. The waiver or alteration will not adversely affect the rights and welfare of the participants; and
- iii. The research could not practicably be carried out without waiver or alteration; and
- iv. Whenever appropriate the participants will be provided with additional pertinent information after participation (45 CFR 46.116(f)(3)).
- v. Screening, recruiting, or determining eligibility. An IRB may approve a research proposal in which and investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
 - The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
 - The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 9.006

Title: Waiver or Alteration of Consent

Section: *Informed Consent*

Date: December 5, 2017

Revised: September 30, 2020

3.1 For research sponsored by the Department of Defense, the following guidelines will be followed:

- i. The IRB may waive the consent process if the research participant(s) do not meet the definition of “experimental participant”
- ii. If the research participant meets the definition of “experimental participant,” the waiver of consent shall not be granted by the IRB unless approval is obtained from the Secretary of Defense.
- iii. “Experimental participant” as defined in Department of Defense Directive 3216.02 shall include:
 1. An individual participating in an activity for research purposes where there is an intervention or interaction for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f), reference (c)). Examples of interventions or interactions include, but are not limited to a physical procedure, a drug, a manipulation of the subject or subject's environment, or the withholding of an intervention that would have been undertaken if not for the research purpose. This does not include:
 - i. Activities carried out for purposes of diagnosis, treatment, or prevention of injury and disease in members of the Armed Forces and other mission essential personnel under Force Health Protection programs of the Department of Defense.
 - ii. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions.
 - iii. Monitoring for compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units. This includes such activities as drug testing, occupational health and safety monitoring, and security clearance reviews.
 - iv. Activities exempt under 32 CFR 219 (reference (c)).

The investigator must request a waiver or alteration of the consent process in Section 7 of Initial Application Part 2.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 10.001

Title: Protected Health Information Identifiers

Section: *Protected Health Information & Research*

Date: December 5, 2017

Reviewed: October 1, 2020

1.0 Purpose

The purpose of this SOP is to define and describe Protected Health Information identifiers.

2.1 Policy

It is the policy of the IRB that the use of Protected Health Information will be in full accordance with regulations at Health and Human Services 45 CFR §46 and other applicable federal, state and local laws.

- A. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule was issued August 13, 2002, with a compliance date of April 14, 2003. The purpose of this rule is to provide additional protections of the privacy rights of participants involved in research. The HIPAA Privacy rule contains requirements designed to ensure that the Protected Health Information of research participants is appropriately used and/or disclosed during the conduct of research. UMCP Health Center is a “covered entity” and complies with HIPAA.
- B. Protected Health Information is defined as any individually identifiable health information. Protected Health Information obtained by any means that is used or disclosed during the course of any research project at this Institution is subject to HIPAA. Only the minimum Protected Health Information necessary to achieve the research objectives can be used.
- C. Individually identifiable Protected Health Information contains one or more of 18 identifiers. If any of the 18 identifiers are associated with the health information, then the information is considered “protected”. De-identification of Protected Health Information requires either:
 1. Removal of all 18 identifiers, or
 2. Documentation by an expert statistician how he/she determined that the risk of participant identification using a subset of identifiers present is very small.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 10.001

Title: Protected Health Information Identifiers

Section: *Protected Health Information & Research*

Date: December 5, 2017

Reviewed: October 1, 2020

D. The 18 identifiers:

1. Names.
2. Postal address information: street address, city, county, precinct, ZIP code (except specified combinations).
3. All elements of dates (except year) related to an individual (e.g. birth, admission, discharge). For participants over 89 years of age, all elements of dates (including year) must be removed.
4. Telephone numbers.
5. Fax numbers.
6. Electronic mail addresses.
7. Social Security numbers.
8. Medical Record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web Universal Resource Locators.
15. Internet protocols address numbers.
16. Biometric identifiers, including finger and voice prints.
17. Full face photographic images [and any comparable images].
18. Any other unique identifying number, characteristic, or code.

**1.0 Purpose**

The purpose of this SOP is to describe the use of Limited Data Sets.

2.1 Policy

It is the policy of the IRB that the use of Limited Data Set will be in full accordance with regulations at Health and Human Services 45 CFR §46.

- 2.2** A researcher with IRB approval and a Data Use Agreement between the researcher and the covered entity can use and disclose Protected Health Information that contains a Limited Data Set without a HIPAA authorization or a waiver of consent granted by the IRB.

The limited data set must have all the identifiers removed, except the following:

- A.** A unique identifying number, characteristic or code (e.g., a registry or study number).
 - B.** Elements of dates (e.g., birth).
 - C.** Town, city, state, and ZIP code.
- 2.3** One of the advantages associated with the use of a Limited Data Set is that it is not subject to the HIPAA requirements of accounting for disclosure of Protected Health Information. Additionally, the limited data set also allows the maintenance of a linked code, which permits re-identification of an individual in the future should the need arise. However, the investigator who is using the Limited Data Set cannot maintain the linked code. The Director will maintain such codes.



1.0 Purpose

The purpose of this SOP is to describe research utilizing medical records.

2.1 Policy

It is the policy of the IRB to use and disclose Protected Health Information in accordance with the HIPAA requirements and federal regulations pertaining to research found at Health and Human Services 45 CFR §46.

2.2 Definitions

- A. Protected Health Information** is individually identifiable health information. Health information means any information, whether oral or recorded in any medium that:
1. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.
- B. De-Identified Protected Health Information** is the removal of all 18 identifiers from the health information (HRPP Policy #[10.001](#))
- C. Designated Record Set** means the medical records and billing records about individuals and records used to make decisions about individuals.
- D. Authorized Investigators:**
1. Any faculty member, student or staff member who is working with a person having ethical/legal access to Protected Health Information materials in a non-research context and who will assume responsibility for maintaining confidentiality safeguards as certified in writing.
- E. Existing Medical Records:** “Existing” medical records is defined as medical records existing at the time of initial submission of the IRB application (e.g., date of the PI signature on the IRB application) and not when the IRB grants final approval and release of the study.



- F. Non-Authorized Investigators:** Person(s) that do not fall within the definition of an authorized investigator shall be deemed a non-authorized investigator.

2.3 Access to Medical Records

Only authorized investigators listed by name in the IRB application shall have access to confidential records to be used for research purposes where participant identifiers are present.

Non-authorized investigators shall have access to confidential records to be used for research purposes with IRB and covered entity approval only when the following conditions are met:

- A.** Approval is obtained to use the records from the covered entity (e.g., medical records department) OR
- B.** The investigator has obtained informed consent/HIPAA authorization from the participant, OR
- C.** All Protected Health Information has been de-identified in accordance with the requirements of HIPAA.

In all cases, the non-authorized investigator shall have received CITI training especially as it regards confidentiality and privacy.

2.4 Exempt Research

Research involving medical records can be exempt provided the records utilized in the research are existing and the data are recorded in such a manner that participants cannot be identified (e.g., either all 18 HIPAA specified identifiers are removed).

2.5 Expedited or Full Board Research

Research involving the study of medical records is not exempt if the investigator records the data in such a manner that participants can be identified either directly or through identifiers linked to the participant or if the study involves prospective collection of records.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 10.003

Title: Research Utilizing Medical Records

Section: *Protected Health Information & Research*

Date: December 5, 2017

Reviewed: October 1, 2020

If participant identifiers must be temporarily maintained in order to permit the investigator to identify additional records for inclusion in the study, informed consent/authorization is required unless the IRB may grant a waiver of informed consent in accordance with the following specific requirements of HIPAA and 45 CFR §46.116(d):

- A. Only the minimum amount of participant identifier data is recorded.
- B. The use or disclosure of Protected Health Information or data, which is not Protected Health Information, involves no more than minimal risk.
- C. The alteration or waiver of informed consent will not adversely affect the rights and welfare of the participants.
- D. The research cannot practicably be carried out without the alteration or waiver.
- E. There must be an adequate plan to protect participant identifiers from improper use and disclosure.
- F. There must be an adequate plan to destroy the identifiers associated with Protected Health Information at the earliest opportunity unless there is a health or research justification for retaining the identifiers or retention is required by law.
- G. Whenever appropriate, the participants will be provided with additional pertinent information after participation.
- H. If identifiers are recorded for the purpose of selecting a prospective participant population and the investigator intends to subsequently solicit informed consent to participate in a prospective study, specific guidelines must be followed regarding initial contact with potential participants. Contact with potential participants should originate with an individual who has the appropriate professional relationship with the potential participant (e.g., primary care physician, counselor, teacher, etc.). If an investigator does not have such a relationship, they should obtain assistance from someone who does. Once the appropriate professional has originated the contact, negotiation for informed consent can begin as with any other research protocol.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 10.003

Title: Research Utilizing Medical Records

Section: *Protected Health Information & Research*

Date: December 5, 2017

Reviewed: October 1, 2020

2.6 DHHS HIPAA Website: <https://www.hhs.gov/hipaa/index.html>



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 10.004

Title: Protected Health Information in
Preparation for Research

Section: *Protected Health Information & Research*

Date: December 5, 2017 **Reviewed:** October 1, 2020

1.0 Purpose

The purpose of this SOP is to describe the process of review of Protected Health Information in preparation for research.

2.1 Policy

It is the policy of the IRB that the review of Protected Health Information in preparation for research will be conducted in full accordance with regulations at Health and Human Services 45 CFR §46.

- 2.2** HIPAA permits an investigator to review medical records containing Protected Health Information in preparation for a research project without obtaining an authorization or a waiver of consent from the IRB. To meet this requirement, the investigator, or other study personnel, must have an ethical-professional access to the Protected Health Information in the medical setting.

The investigator must file a request for access with the pertinent institution (e.g., UMCP Student Health Center, local hospital or clinic). If the PHI is not contained within the medical record, the request should be filed with the IRB. The investigator must certify:

- A.** Review of Protected Health Information will be conducted solely to determine the feasibility of a research project or for similar purposes in preparation for research.
- B.** Protected Health Information may not be recorded, copied, or removed from the records repository in the course of review.
- C.** Protected Health Information that is accessed is solely for research purposes.

If an investigator intends to record any Protected Health Information for the express purpose of contacting prospective research participants, the appropriate IRB application and associated informed consent documents must be submitted and approved by the IRB prior to the review of the medical records.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 11.001

Title: Continuing Review

Section: *Continuing Review*

Date: December 5, 2017

Revised: October 7, 2020

1.0 Purpose

The purpose of this SOP is to describe the IRB's process for conducting continuing review.

2.1 Policy

It is the policy of the IRB that continuing review will be conducted in accordance with Health and Human Services regulations at 45 CFR §46.109(e) and OHRP guidance on continuing review (July 11, 2002).

Expedited continuing and full board protocols are approved for one year at a time and must be renewed annually by completion of a Continuing Review Application.

Continuing Review applications are no longer required for projects approved through the Expedited review path according to (45CFR46.109(f)(1)(i)) unless the IRB determines there is a need for a Continuing Review at the time of Initial Approval or after an Amendment that has modified the initial project. However, the UMD HRPP has determined to require Continuing Review applications for projects approved through the Expedited review path as a means of Quality Assurance. Expedited-approved projects will submit a Continuing Review prior to expiration or within 30 days post-expiration to continue their project. If the Continuing Review is not submitted within 30 days post-expiration the project will be administratively closed.

Projects approved through the Expedited review path will have their Continuing Review applications reviewed by a Research Compliance Analyst in the IRB Office and will receive a determination of 'Acknowledged', unless it was determined during review of the Initial Application that the IRB Chair must review the Continuing Review for 'Approval'.

Continuing Review has to occur as long as the research remains active for long-term follow-up of subjects, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related interventions. Continuing review of research has to occur when the remaining activities are limited to collection of private identifiable information.

If an investigator does not provide continuing review information to the IRB, or the IRB has not approved the protocol by the expiration date, the investigator will be instructed to stop all research activities, including recruitment, enrollment, interventions, and interactions, and collection of private identifiable data, and to stop all interventions and interactions on current participants, unless the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 11.001

Title: Continuing Review

Section: *Continuing Review*

Date: December 5, 2017

Revised: October 7, 2020

To maintain compliance with OHRP guidance, Continuing Reviews submitted 30 days or more prior to expiration will have the review begin within the 30 days period prior to expiration.

New enrollment of participants is not allowed after the expiration of IRB approval.

2.2 Risk Level

All human participant studies are subject to continuing review based on the level of risk as assessed by the IRB. Research approved previously by expedited review is considered eligible for expedited review at the time of its regular continuing review, if, during the course of the study, the risks of the study have not increased. Projects that were initially reviewed by the full board continue to receive full board review unless the IRB determined at the initial review during the full board meeting that the study meets the specific criteria for expedited review.

2.3 Continuing Review Submission Requirements

- A. It is the responsibility of the PI to submit the IRB Application for Continuing Review, which must include informed consent/assent forms (updated as necessary) in sufficient time to allow the IRB to complete a substantive and meaningful review of the research, as well as provide the PI with a timely, written response prior to the expiration date indicated on the current IRB approval letter.
- B. The PI will receive four (4) reminders their project is due to expire. IRBNet will send these courtesy reminders 60, 45, 30, and 15 days prior to expiration of IRB approval. IRBNet will send another email on the date of expiration if the Continuing Review has not yet been approved.
- C. If the IRB, or expedited reviewer(s), determines that a project requires review more often than annually, the investigator will be so notified at the time of initial review and/or at the time of continuing review. Factors which determine the frequency of continuing review are described in HRPP policy # [3.010](#).

2.4 Pre-Review

The IRB staff is responsible for pre-review of projects undergoing continuing review. At any time, the individual staff person may seek guidance and/or assistance from either the HRPP staff or Director during the pre-review process.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 11.001

Title: Continuing Review

Section: *Continuing Review*

Date: December 5, 2017

Revised: October 7, 2020

- A.** The project file is accessed via IRBNet and IRB number, title(s) and study personnel listing are checked for accuracy and training for personnel is verified. The current application for continuing review will be compared with the previous year's application, as well as other documents found in the protocol record as necessary, with particular attention paid to the types of consent documents. The reviewer(s) are provided with the complete protocol. When conducting review using the expedited procedure, the reviewer receives, and reviews all submitted information including the complete protocol history. It is expected that primary and secondary reviewers perform an in-depth review of all pertinent documentation.
- B.** The new consent form(s) to be used during the next IRB approval period will be compared with the version last approved by the IRB to determine if the correct version of the consent form(s) has (have) been provided. In addition, the consent document will be closely checked for typographical or formatting errors and if any changes have been made to the consent document.
- C.** Discrepancies or omissions in the Continuing Review Application will result in an email to the PI and SI requesting clarification and/or correction to appropriate forms. If the number of problems in the application are of such magnitude that IRB review is not possible, the full application and supporting documents will be sent back to the PI for revision and resubmission of the revised application and/or consent document(s).
- D.** In situations of possible non-compliance, the HRPP Director will be notified. A complete review of the IRB study record will be performed by the HRPP staff to determine what further action should be taken in accordance with HRPP Policy #[14.001](#).
- E.** For full board continuing reviews, copies of all correspondence (emails or letters) resulting from the pre-review process will be accessible via IRBNet to all IRB members. In addition, the IRB staff will contact the assigned reviewers to inform them of unresolved problems or concerns.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 11.001

Title: Continuing Review

Section: *Continuing Review*

Date: December 5, 2017

Revised: October 7, 2020

2.5 Expedited Continuing Review

- A. If determined to need a Continuing Review during the Initial Application Expedited review, applications for continuing review will be assigned to the IRB Chair. Otherwise, they will be reviewed by a Research Compliance Analyst and receive an determination of Acknowledged.
- B. The expedited reviewer will determine whether or not increased monitoring and/or more frequent continuing review is required in accordance with HRPP Policy#[3.010](#).
- C. IRB approval periods for protocols reviewed by the expedited method begin as of the date of completion of the review (initial), which is the date of the review letter. Approval periods cannot exceed one year. IRB approval therefore expires one year later or sooner if the expedited reviewer sets a more frequent continuing review date.

For example: if expedited review was completed on February 17, 2005, and the reviewer set an approval period of one year, IRB approval is valid until February 16, 2006. This means that IRB approval is in force until 11:59 pm February 16, 2006. As of midnight all research activity must cease unless IRB approval has been granted.

2.6 Expedited Review Actions

- A. **Acknowledge or Approval**
No modifications or clarifications are required. All of the criteria for IRB approval specified in Health and Human Services regulations at 45 CFR §46.111 are satisfied. The investigator will be notified of the approval or acknowledgement electronically and is authorized to continue the study.
- B. **Approval with Specific Changes**
Minor clarification(s) or information concerning the protocol is necessary for completion of the record. This action is only taken when the clarification(s) is (are) minor and does not impact protection of human participants. The investigator will be notified of the modifications electronically and asked to make the changes and return the materials before final approval for continuing review can be granted.



Failure to respond to the IRB continuing review clarification letter may result in the full IRB revoking approval of the study. In such a case, all research related activities must immediately cease, unless an extension is granted by the IRB Chair in consideration of a written request from the PI. The IRB will be notified of all extensions granted by the IRB Chair.

The Analyst will review and send the response to the IRB Chair who will grant approval or request additional modifications.

C. Tabled

Only the fully convened IRB may table a project or continuing review.

The investigator will be notified in writing as to the nature of the required modifications/clarifications. During the remaining IRB approval period, the investigator is authorized to continue the research. The investigator response will be reviewed by the IRB. If all modifications have been adequately addressed, the continuing review and response will be assigned to the next available IRB agenda for review.

If the PI fails to respond to the IRB's continuing review determination letter within the remaining IRB approval period, the protocol has, or will be, classified as administratively closed. If IRB approval expires, all research-related activities must immediately cease.

D. Referred for Full IRB Review

IRB members assigned to perform an expedited review can refer the project for review by the full IRB.

2.7 Full IRB Review Procedure

- A.** If the research initially required full IRB approval, the Continuing Review Application must also be approved by the full IRB. Unless at the initial approval it was determined that the project involves no greater than minimal risk and no additional risks have been identified then the application for continuing review can be reviewed as expedited continuing.
- B.** Applications for continuing review are scheduled for full IRB consideration at the monthly IRB meeting, if quorum can be obtained. Each attending member will



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 11.001

Title: Continuing Review

Section: *Continuing Review*

Date: December 5, 2017

Revised: October 7, 2020

receive, at least one week in advance, all continuing review applications and associated consent/assent documents to be considered at the meeting and have access to the complete protocol. IRB members are asked to review, as necessary, the complete IRB protocol record.

- C. A primary reviewer will be assigned to perform a thorough review of the application. He/she will interact with the IRB staff involved in the pre- review as necessary, contact the investigator in order to resolve any concerns prior to the meeting, and review the project at the meeting when necessary.
- D. In order to facilitate continuing review, a Full Board Continuing Review Reviewer Guidance document is made available to reviewers.
- E. The primary reviewer will present to the full IRB the results of his/her review and any remaining concerns will be discussed by the members who are also expected to have reviewed the application and the consent/assent documents. Each protocol will be voted on separately in accordance with IRB policy (HRPP Policy # [2.011](#)).
- F. The IRB will determine whether or not increased monitoring and/or more frequent continuing review is required in accordance with HRPP policy #[3.010](#).
- G. IRB approval periods for projects reviewed by the full board begin as of the date of initial review. The month and day of this approval will not change. If the IRB reviews and approves a continuing review prior to the expiration date, the new approval period will begin after the expiration date. Investigators will receive an “effective date” of the IRB determination. This is not the approval date.

Approval periods cannot exceed one year, which is defined as one year from the date of IRB review. IRB approval, therefore, expires one year later, or sooner if the IRB sets a more frequent continuing review date.



2.8 Full IRB Actions

A. Approval

No modifications or clarifications are required. All of the criteria for IRB approval specified in Health and Human Services regulations at 45 CFR §46.111 are satisfied. The investigator will be notified of the re-approval in writing and is authorized to continue the study.

B. Approval with Specific Changes

This category is restricted to modifications/clarifications, which are not considered to be substantive in nature.

This action is taken when the clarification(s) is (are) minor and does not impact protection of human participants and/or the approvability of the consent document(s). The investigator will be notified of the re-approval in writing and asked to make the necessary modifications and return the materials before final approval of continuing review can be granted.

Failure to respond to the IRB continuing review modification letter in a timely fashion may result in the expiration of the project. In such a case, all human research related activities must immediately cease.

The investigator will be notified in writing as to the nature of the required modifications/clarifications. During the remaining IRB approval period, the investigator is authorized to continue the research. When the investigator complies, in writing, with all requirements as determined by the IRB Chair, approval will be granted.

C. Tabled

Only the fully convened IRB may table a project or continuing review. The investigator will be notified in writing as to the nature of the required modifications/clarifications. During the remaining IRB approval period, the investigator is authorized to continue the research. The investigator response will be reviewed by the IRB. If all modifications have been adequately addressed, the continuing review and response will be assigned to the next available IRB agenda for review.



If the PI fails to respond to the IRB's continuing review determination letter within the remaining IRB approval period, the protocol has, or will be, classified as administratively closed. If IRB approval expires, all research-related activities must immediately cease.

D. Decline to Complete Review

This category is restricted to applications, which are deficient and preclude the IRB from performing a substantive and meaningful review. The investigator will be instructed in writing to revise the application in accordance with IRB requirements. During the remaining IRB approval period, the investigator is authorized to continue the research.

If the PI fails to respond within the remaining IRB approval period, the protocol will expire. If IRB approval expires, all research-related activities must immediately cease.

E. Disapproved

The IRB has a serious concern regarding participant safety and/or compliance. The protocol will be suspended or possibly terminated and a report submitted to OHRP in accordance with HRPP policy # [14.002](#). No new participants can be accrued. All research-related activities must cease and the full IRB will make a determination if currently enrolled participants may continue participation in the study. The Institutional Official and the PI's departmental chair will be notified.

2.9 IRB Approval Notification

Upon IRB approval of a research project, a letter of approval will be published in IRBNet. The letter provides a summary of investigator responsibilities and also reminds investigators that changes in research activity may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to participants.

The currently approved consent/assent forms should be kept on file as the master copies and all outdated consent/assent forms must be destroyed as they are no longer valid.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 11.001

Title: Continuing Review

Section: *Continuing Review*

Date: December 5, 2017

Revised: October 7, 2020

Initial and amended informed consent documents signed by the participant remain in effect for the duration of the participant's participation in the study. Therefore, previously enrolled participants are not required to be re-consented each year following continuing review, unless the IRB approves a change during the continuing review process, which requires re-consent of participants (e.g., participant notification of new risks or changes in protocol.)

2.10 IRB approval terminated

If a PI fails to submit the IRB Application or respond to the IRB review letter in sufficient time to allow the IRB to complete its review and grant approval before the end of the current IRB approval period, the protocol will be classified as closed.

2.11 Final progress reports

When a project is terminated or completed, the PI must immediately notify the IRB by completing the Closure Report Form and submitting this through IRBNet.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 11.002

Title: Suspension and Termination

Section: *Continuing Review*

Date: December 5, 2017

Reviewed: October 7, 2020

1.0 Purpose

The purpose of this SOP is to describe the conditions under which suspension and termination apply and the process involved.

2.1 Policy

Suspension of IRB approval is a directive of the convened IRB or IRB Chair or IRB Director either to temporarily or permanently stop some or all previously approved research activities short of permanently stopping all previously approved research activities.

Suspended protocols remain open and require continuing review. Termination of IRB approval is a directive of the convened IRB to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed.

- A. The IRB Chair or Director may suspend research to ensure protection of the rights and welfare of participants. Suspension directives made by the IRB Chair or IRB Director must be reported to and reviewed by the convened IRB. Research may only be terminated by the convened IRB. Terminations of protocols approved under expedited review must be made by the convened IRB.
- B. When study approval is suspended or terminated by the convened IRB or an authorized individual, in addition to stopping all research activities, the convened IRB or individual ordering the suspension or termination will notify any subjects currently participating that the study has been suspended or terminated. The convened IRB or individual ordering the suspension or termination will consider whether procedures for withdrawal of enrolled subjects are necessary to protect the rights and welfare of participants, such as: transferring participants to another investigator; making arrangements for care or follow-up outside the research; allowing continuation of some research activities under the supervision of an independent monitor; or requiring or permitting follow-up of participants for safety reasons.
- C. If follow-up of participants for safety reasons is permitted/required by the convened IRB or individual ordering the suspension or termination, the convened IRB or individual ordering the suspension or termination will require the participants should be so informed and that any adverse events/outcomes be reported to the IRB and the sponsor.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 11.002

Title: Suspension and Termination

Section: *Continuing Review*

Date: December 5, 2017

Reviewed: October 7, 2020

- D.** It is the policy of the IRB that the following incidents will be promptly reported to OHRP and Department or Agency heads (if applicable) in accordance with Health and Human Services regulations at 45 CFR §46.103(b) (5) or to other federal agencies when the research is overseen by those agencies:
1. Any unanticipated problem involving risk to the participant or others,
 2. Any serious noncompliance,
 3. Any continuing noncompliance,
 4. Any suspension or termination of IRB approval,
 5. Any internal or external holds placed on IRB approved protocols (HRPP [14.002](#))



1.0 Purpose

The purpose of this SOP is to describe the process for requesting changes to an approved protocol.

2.1 Policy

It is the policy of the IRB that review of all requests for changes in approved protocols will be conducted in full accordance with regulations at Health and Human Services 45 CFR §46.

A. Introduction

Any proposed change in a project which affects the human participants must be reviewed and approved by the IRB prior to implementation except when an immediate change is necessary to eliminate a hazard to the participants, or to provide participants with new information on adverse events or research results considered essential to a participant's decision whether to continue participating.

B. Submission Requirements

Investigators must submit:

1. Amendment Form via IRBNet.
2. Complete description of the changes requested.
3. Revised protocol (as appropriate).
4. Revised consent/assent document(s) (as appropriate).

[**NOTE:** The IRB files must contain a complete and accurate description of the research. Therefore, changes indicated in the Amendment Form must be described clearly.]

5. When a change in protocol is the result of a new or revised grant application, a copy of the complete grant narrative must accompany the Amendment Form.

C. IRB Review

As a Request for Change in Protocol form is received in the HRPP office, the IRB staff will pre-review and document the requests to determine whether the requested change is indeed minor.

1. The change is **minor** in nature and the risk to the participant is minimal. Minor changes include addition of procedures found on the expedited review list (e.g., minor change in eligibility requirements, deletion of an intervention, and change in follow-up schedules). Minor changes are approvable under expedited review. It must be documented that it is a



minor change. While re-consent of current participants utilizing the revised IRB- approved consent document is normally not required by the IRB, the PI must provide a plan, as necessary, for notification of current participants. Other changes such as changes in telephone numbers, addition or deletion of staff, and correction of typographical errors will be handled by a Research Compliance Analyst as an administrative review and will receive a determination of Acknowledged.

2. The change is **major**, but does not require immediate implementation in order to reduce a hazard to participants. Examples of major changes include: changing the treatment or revising eligibility requirements. The changes cannot be implemented until reviewed by the full IRB for projects presenting greater-than-minimal-risk. Re-consent of current participants utilizing the revised IRB-approved consent document or addendum is normally required.
3. The change is **significant** and requires **immediate implementation** in order to decrease risk to participants and requires full disclosure to the participants immediately. These changes may include: addition of a major risk resulting from a reported adverse event or other major changes enacted to reduce risk to participants. Re-consent of current participants utilizing the revised IRB-approved consent document or addendum is required. A witness may be required during the re-consent process.

All IRB members have access to all submitted materials for the review of modifications to previously approved research by the convened IRB via IRBNet. It is expected that primary and secondary reviewers will perform an in-depth review of all pertinent documentation. All other IRB members will review all provided materials in enough depth to discuss the information at the convened meeting. (HRPP Policy [2.009](#))

D. Change to Eliminate Immediate Risk Prior to IRB Approval

If a change is initiated without any IRB approval in order to eliminate immediate hazards to the participants or to provide essential information to the participants, the IRB must be notified as soon as possible, but no later than two (2) business days from the time the change was initiated. If the change was initiated for all participants, the IRB Request for Change in Protocol must be completed.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 12.001

Title: Request for Changes

Section: *Amendments to Approved Projects*

Date: December 5, 2017

Revised: October 7, 2020

1. The investigator is authorized to implement changes without IRB approval in order to eliminate apparent immediate hazards to participants.
 2. The IRB chair or designee has no authority to approve more than minor changes even if needed to eliminate immediate hazardsto participants.
- E. When conducting review using the expedited procedure, the reviewer has access and reviews all submitted information including the complete protocol history in IRBNet. The reviewer(s) complete the Criteria for Approval guidance to determine whether the modifications meet the criteria allowing review using the expedited procedure, and if so, whether the research with the proposed modifications meets the regulatory criteria for approval. (HRPP Policy [2.009](#))

For full review, at the meeting, the primary reviewer presents an overview of the modifications and leads the IRB through the completion of the regulatory criteria for approval. (HRPP Policy [2.009](#))



1.0 Purpose

The purpose of this SOP is to describe the procedure to ensure prompt reporting to the IRB, appropriate institutional officials, sponsor, coordinating center, and the appropriate regulatory agencies of unanticipated problems involving risks to participants or others.

2.1 Definitions

A. **Unanticipated Problems Involving Risk to Participants or Others:**

This term is defined as an adverse event that is (1) unexpected, (2) serious, and (3) related or possibly related to participation in the research. Unanticipated problems also include unexpected adverse events, regardless of severity, that the IRB determines represent risk to participants or others. Unanticipated problems also includes events that are not categorized as adverse events and are not directly related to an individual subject's participation in a study, but represent risk to participants or others.

Example: Events that could lead to a breach of confidentiality or privacy provisions such as the unanticipated loss or theft of files or that in anyway might subject the research participant to a higher degree of risk than anticipated in the research protocol.

B. **Adverse Event (AE):**

This term is defined as any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article.

C. **Serious Adverse Event (SAE):**

This term is defined as death; a life threatening experience; hospitalization (for a person not already hospitalized); prolongation of hospitalization (for a patient already hospitalized); persistent or significant disability or incapacity; congenital anomaly and/or birth defects; or an event that jeopardizes the subject and may require medical or surgical treatment to prevent one of the preceding outcomes.

D. **Unexpected Adverse Event (UAE):**

This term is defined as any adverse event and/or reaction, the specificity or severity of



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 13.001

Title: Reportable Events

Section: *Unanticipated Problems & Adverse Events*

Date: December 5, 2017

Reviewed: October 7, 2020

which is not consistent with the informed consent, current investigator brochure or product labeling. Further, it is not consistent with the risk information described in the general investigational plan or proposal.

E. Related:

An event is “related” if it is likely to have been caused by the research procedures.

F. Substantive Action:

An action taken by an IRB that materially alters the substance and meaning of a protocol, informed consent form or process, or investigator status, including, but not limited to, restriction, suspension or termination of a study or investigator participation, and actions taken to prevent future occurrence(s) of the AE in research.

G. Unexpected Death:

The death of a research subject in which a high risk of death is not projected, as indicated by the written protocol, informed consent form, or sponsor brochure. This definition does not include deaths associated with a terminal condition unless the research intervention clearly hastened the subject’s death. A subject’s death that is determined to be clearly not associated with the research is also not an “unexpected death” for purposes of the reporting requirements of these procedures.

3.1 Policy

It is the IRB’s policy to comply with Health and Human Services regulations at 45 CFR §46.103(b)(5)(1)(i) to have policies and procedures that ensure reporting of all unanticipated problems involving risk to participants or others to the IRB, regulatory agencies, and institutional officials.

3.1 The following problems must be reported to the IRB within 48 hours using the Problem Report form:

- A.** Any physical or psychological harm experienced by a participant, which in the opinion of the principal investigator, is both unexpected and related.

Harm is “unexpected” when its specificity and severity are not accurately reflected in the consent document.

Harm is “related to the research procedures” if in the opinion of the principal



investigator, it is more likely than not to be caused by the research procedures or if it is more likely than not the event affects the rights and welfare of current participants.

B. Information that indicates a change to the risks or potential benefits of the research. For example:

- 1.** An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits might be different from those initially presented to the IRB.
- 2.** A paper is published from another study that shows that the risks or potential benefits of your research might be different from those initially presented to the IRB.

C. A breach of confidentiality.

D. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant

E. Incarceration of a participant in a protocol not approved to enroll prisoners.

F. An event that requires reporting to the sponsor.

G. Sponsor imposed suspension.

H. Participant complaint.

I. Protocol deviation.

3.2 External Reportable Events

A. The IRB Chair reviews problem reports and determines whether each is an unanticipated problem involving risks to participants or others. If the report is an unanticipated problem involving risks to participants and others (UPIRPO), it is referred to the convened IRB for review. If it is not an UPIRPO, the IRB Chair will



review and acknowledge the report. The IRB Chair also considers whether each report involves noncompliance. If so, the noncompliance policy is followed. If the IRB chair determines that the report is neither an unanticipated problem involving risks to participants or others nor noncompliance, it is filed and no further action is taken.

- B.** The IRB Chair will take all actions necessary to protect human participants including suspension or termination of the study (HRPP Policy # [14.001](#)). Investigators may also make changes to the research without prior approval by the IRB when necessary to eliminate apparent immediate hazards.
- C.** If referred for full IRB review, one (1) IRB reviewer is assigned to review the Report of Unanticipated Problem(s) or Adverse Event(s) Involving Risk. This member is provided and expected to review, in depth, copies of:
1. The Report of Unanticipated Problem Involving Risk and all submitted supporting materials.
 2. The current consent document.
 3. The protocol application.
 4. The industry protocol (if one exists).
 5. The investigator's brochure (if one exists).
- D.** All IRB members are provided and are expected to review, be familiar with, and be prepared to discuss copies of:
1. The Report of Unanticipated Problem(s) or Adverse Event(s) Involving Risk and all submitted supporting materials.
 2. The current consent document.
- E.** The primary reviewers present the event or problem and lead the discussion. The IRB discusses and votes on whether the event or problem represents an unanticipated problem involving risks to participants or others as defined above. If the IRB determines by majority vote that the event or problem represented an unanticipated problem involving risks to participants or others, the SOP on Reporting to Regulatory Agencies and Institutional Officials will be followed (HRPP Policy #[14.001](#) and #[14.002](#)). If the IRB determines that the problem is not an unanticipated problem involving risks



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 13.001

Title: Reportable Events

Section: *Unanticipated Problems & Adverse Events*

Date: December 5, 2017

Reviewed: October 7, 2020

to participants or others, the IRB determination overrules the determination of the chair and no further action is taken. The IRB determination of whether the problem is an unanticipated problem involving risks to participants or others is documented in the minutes.

- F.** The IRB considers the following actions on all reportable events or problems:
- 1.** No action.
 - 2.** Modification of the research protocol.
 - 3.** Modification of the information disclosed during the consent process.
 - 4.** Additional information provided to past participants.
 - 5.** Notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research).
 - 6.** Requirement that current participants re-consent to participation.
 - 7.** Modification of the continuing review schedule.
 - 8.** Monitoring of the research.
 - 9.** Monitoring of the consent.
 - 10.** Suspension of the research.
 - 11.** Termination of the research.
 - 12.** More information sought pending a final decision or
 - 13.** Referral to other organizational entities (e.g., legal counsel, risk management).



1.0 Purpose

The purpose of this SOP is to: **1)** define noncompliance, **2)** describe categories of noncompliance, **3)** describe procedures for reporting noncompliance to the IRB, **4)** address IRB actions, and **5)** reporting noncompliance to OHRP and Department or Agency heads.

2.1 Definitions

- A. **Noncompliance** is defined as the failure to comply with any Health and Human Services regulations, and/or IRB requirements. Noncompliance is assessed as non-serious, serious, or continuing.
- B. **Incident of noncompliance** is defined as a proven assertion of non-compliance.
- C. **Serious noncompliance** is defined as failure to comply with Health and Human Services regulations, and/or IRB requirements, which in the judgment of the convened IRB, places human participants at unacceptable risk, decreases potential benefits to participants, compromises the integrity of the HRPP, or results in non-disclosure of pertinent information to all participants thereby compromising informed consent.

Example 1: Use of an outdated consent document where the changes are material to the participant's consent and, therefore the participant was unable to make an informed decision (e.g., new information about risks).

Example 2: Failure to have the participant sign the consent form.

Example 3: Failure to submit a Request for Change prior to implementing a change and the change has impact on the risk/benefit relationship of the research and/or the informed consent (e.g., addition of blood draws).

Example 4: Conduct of a study after IRB approval expiration.

Example 5: Failure to obtain IRB approval of non-exempt research.

Example 6: Failure to report to the IRB an unanticipated problem involving risk to the participant or others, which impacts the risk/benefit relationship of the study and/or informed consent (e.g., a participant develops depression after a particular psychological technique is implemented and is not described in the informed consent form).



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 14.001

Title: Noncompliance

Section: *Compliance*

Date: December 5, 2017

Reviewed: October 7, 2020

D. Continuing noncompliance is defined as a pattern of noncompliance that, in the judgment of the convened IRB, suggests a likelihood that instances of noncompliance will continue without intervention. “Continuing noncompliance” also includes failure to respond to a request to resolve an episode of noncompliance. “Continuing noncompliance” includes:

1. Multiple incidents of serious or non-serious noncompliance in a twelve (12) month period, which occurs in any one research protocol. The incidents of noncompliance may involve one specific issue or different issues.

Example: During a routine audit of the PI’s research records, ten of fifty consent forms obtained during the last twelve months were not properly signed and dated.

2. Multiple incidents of serious or non-serious noncompliance in a twelve month period carried out by the same individual in multiple research protocols. The incidents of noncompliance may involve one specific issue or different issues.

Example: During a routine audit of the PI’s research records for six studies, multiple protocol violations were identified, which included failure to record lab values, participants seen outside of window, participants signing outdated consent forms, and lack of re-consent of participants in a timely manner.

The IRB reserves the right to judge noncompliance as continuing in circumstances that do not meet the above definition.

E. Allegation of noncompliance is defined as an unproven assertion of noncompliance.

F. Serious allegation of noncompliance is defined as an unproven assertion of noncompliance with grave implications.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 14.001

Title: Noncompliance

Section: *Compliance*

Date: December 5, 2017

Reviewed: October 7, 2020

3.1 Policy

All members of the University community involved in human participant research are expected to comply with the ethical standards of professional conduct in accordance with federal and state regulations and UMCP and IRB policies governing the conduct of research involving human participants. Therefore, it is the policy of the IRB that investigators and research staff must immediately report to the HRPP office any allegations or incidents of noncompliance.

All allegations or incidents of noncompliance will be promptly investigated in order to ensure ongoing adequate protection of the rights and welfare of research participants. Confidentiality will be preserved and due process utilized.

Serious or continuing noncompliance and suspensions or terminations of IRB approval must also be promptly reported to OHRP, and department or agency heads in accordance with HRPP Policy # [14.002](#).

A. Reporting Noncompliance

1. Investigators and research staff must report all allegations or incidents of noncompliance immediately to the HRPP office(301- 405-4212).
2. A report of an allegation or incident of noncompliance can be submitted to the HRPP office via a letter, email, or telephone call from any source.

B. Procedure for Handling an Allegation of Noncompliance

1. Receipt of the allegation of noncompliance will be documented.
2. The investigator will be informed of all allegations of noncompliance.
3. Confidentiality and compliance with policies and procedures will be maintained at all times.
4. The Chair and Director will investigate the allegation of noncompliance to determine whether it is true or has no basis in fact. If the Chair and Director are unable to conduct the investigation on their own, others may be requested to assist.
5. If the Chair and Director determine that the allegation of noncompliance has no basis in fact, this determination is communicated to the investigator and no other action is taken. If the Chair and Director determine that the



allegation of noncompliance is true, the Institutional Official is informed and it is handled below as an incident of noncompliance.

C. Procedure for Handling an Incident of Noncompliance

1. Receipt of the incident of noncompliance will be documented.
2. The investigator will be informed of all incidents of noncompliance.
3. Confidentiality and compliance with policies and procedures will be maintained at all times.
4. The Chair and Director will investigate the incident of noncompliance to determine whether it is serious or continuing. If the Chair and Director are unable to conduct the investigation on their own, others may be requested to assist.

CI. Procedure for handling an incident of noncompliance determined by the Chair and Director to be neither serious nor continuing.

1. Receipt of the incident of noncompliance will be documented.
2. The investigator will be informed of all incidents of non-compliance.
3. Confidentiality and compliance with policies and procedures will be maintained at all times.
4. The Chair and Director will investigate the incident. If Chair and Director determine the incident to be neither serious nor continuing, then the investigator and the IRB will be informed of the determination by letter or email. It will be filed and no further action taken.

CII. Review by the Convened IRB of Noncompliance Determined by the Chair or Director to be Serious or Continuing.

1. The IRB Chair and Director reviews and determines that an allegation or incident on non-compliance is serious or continuing. The Chair is charged with internal review of any incident of allegation or noncompliance.
2. The IRB Chair and Director will take all actions necessary to protect human participants including suspension of the study.
3. All findings of serious or continuing non-compliance referred to the IRB will be reviewed at a convened meeting. All IRB members are provided with and expected to review, be familiar with, and be prepared to discuss copies of:



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 14.001

Title: Noncompliance

Section: *Compliance*

Date: December 5, 2017

Reviewed: October 7, 2020

- a. All documents relevant to the allegation
- b. The last approval letter from the IRB
- c. The last approved IRB protocol; and
- d. The last approved consent document.

Two IRB reviewers are assigned to review the incident or allegation in depth. The primary reviewers present the event or problem and lead the discussion. The IRB discusses and votes on whether it represents serious or continuing noncompliance. If the IRB incident or allegation is serious the SOP on Reporting to Regulatory Agencies and Institutional Officials will be followed (See HRPP policy #[14.001](#) and # [14.002](#))

F. At this stage, the IRB may:

1. Find that there is no issue of non-compliance;
2. Find that there is noncompliance that is neither serious nor continuing and an adequate corrective action plan is in place;
3. Find that there is serious or continuing non-compliance and approve any changes proposed by the IRB Chair and Director
4. Find that there may be serious or continuing non-compliance and direct that a formal inquiry (described below) be held; or
5. Request additional information.

G. If there is a finding of serious or continuing non-compliance, the following actions can be considered for any corrective action plan:

1. Increase monitoring of the study by the Quality Assurance Analyst
2. Required interim reports from PI.
3. Reported internal audits be conducted by the PI and/or study personnel.
4. Monitoring of the consent process by the IRB Specialist or IRB members.
5. More frequent continuing review.
6. Disclosure to the participant information which may affect the participant's willingness to continue in the study.
7. Required additional training of the principal investigator and or/study personnel in the protection of human participants.
8. Suspension of the study.
9. Termination of the study.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 14.001

Title: Noncompliance

Section: *Compliance*

Date: December 5, 2017

Reviewed: October 7, 2020

10. Suspension of all principal investigator's studies pending the completion of an audit.
11. Recommendation of the IO that a letter of reprimand is placed in the principal investigator's personnel file or the file of other study personnel.
12. Recommendation to the IO that the principal investigator's privilege to conduct research be suspended for a specific period of time or terminated.
13. Recommendation to the IO that the principal investigator's employment or employment of specific study personnel be terminated.
14. Recommendation to the IO that the case be referred for further action or investigation by the Professional Conduct Committee.
15. Recommendation to the IO that whistleblower protection is needed for the complainant.

H. Reporting noncompliance to federal agencies. All noncompliance determined by the Chair and Director to be serious or continuing noncompliance will be reported to OHRP, and Federal Department or Agency Heads in accordance with HRPP Policy # [14.002](#).



1.0 Purpose

The purpose of this SOP is to describe the procedure to ensure prompt reporting to OHRP or Department and Agency Heads: 1) unanticipated problems involving risk to the participants or others, 2) serious or continuing noncompliance, and 3) suspensions or terminations of approved research by the IRB.

2.1 Definitions

- A. **Unanticipated problems involving risks to participants or others** are defined as any problem that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm.
- B. **Serious noncompliance** is defined as failure to comply with any Health and Human Services regulations, and/or IRB requirements that places human participants at unacceptable risk or results in non-disclosure of pertinent information to all participants thereby compromising informed consent.
- C. **Continuing noncompliance** is defined as: 1) multiple incidents of serious or non-serious noncompliance in a twelve (12) month period, which occurs in any one research protocol, or 2) multiple incidents of serious or non-serious noncompliance in a twelve (12) month period carried out by the same individual in multiple research protocols. The incidents of continuing noncompliance may involve one specific issue or different issues.
- D. **Suspension or termination of IRB approval of research** is defined as a mandatory directive to the investigator in writing to suspend or terminate some or all research activities conducted under an IRB- approved protocol. Such directives may be issued as a result of decisions made by either the full IRB at a convened meeting or by the IRB Chair in order to eliminate apparent immediate hazards to the participants or others
- E. **Internal Study Hold** is defined as a mandatory directive by the IRB to the investigator in writing to suspend further participant accrual on an IRB approved protocol. Such directives may be issued when the IRB has a concern about unresolved adverse event or serious problem reports, or other issues, which impact participant safety.



- F. External Study Hold** is defined as a mandatory directive by the sponsor or cooperative group, to the investigator in writing to suspend further participant accrual on an IRB approved protocol. Such directives are usually issued for planned study holds to evaluate reported problematic therapeutic techniques.

3.1 Policy

It is the policy of the IRB that the following incidents will be promptly reported to OHRP and Department or Agency heads (if applicable) in accordance with Health and Human Services regulations at 45 CFR §46.103(b) (5) or to other federal agencies when the research is overseen by those agencies: 1) any unanticipated problem involving risk to the participant or others, 2) any serious noncompliance, 3) any continuing noncompliance, 4) any suspension or termination of IRB approval, and 5) any internal or external holds placed on IRB approved protocols.

Reporting to OHRP and other relevant federal agencies unanticipated problems involving risk to the participant or others, which occur at institutions not under the jurisdiction of the IRB are the responsibility of the external institution.

- A.** The IO is responsible for the prompt submission of all required written reports to OHRP, and/or Department or Agency heads.
- B.** The IO may notify OHRP verbally in advance of a written report when the incident is particularly serious.
- C.** All required reports will be submitted no later than five (5) business days from the time the full IRB makes a final determination concerning the incident.
- D.** If the study is conducted or funded by any Federal Agency other than DHHS that is subject to "The Common Rule", the report is sent to OHRP or the head of the agency as required by the agency.
- E.** Information to be included in written reports:
 - 1.** Name of the institution.
 - 2.** Project number.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 14.002

Title: Reporting Incidents to Department & Agency
Heads

Section: *Compliance*

Date: December 5, 2017

Reviewed: October 7, 2020

F. Notification of Institutional Officials

Copies of the letter sent to the OHRP and any necessary supporting documents must be provided to:

1. The individual(s) directly responsible for the noncompliance.
2. The PI.
3. The IRB.
4. Chair of the PI's Department.
5. The Federal sponsor.
6. Other Institutional officials as determined by the IRB.

G. Health and Human Services Office of Human Research Protection (OHRP)

1. Within five (5) business days of the full Board decision, the IO will send a formal letter to the OHRP Director of Compliance Oversight. The letter must include the following:
 - a. Identification of the protocol.
 - b. Funding of the protocol (federally or non-federally funded, commercially sponsored).
 - c. Timeline and description of the noncompliance.
 - d. Copy of the IRB application and applicable consent document(s).
 - e. Applicable reports from IRB consultants.
 - f. Other documentation pertaining to the event.
 - g. Corrective action plan approved by the full IRB.
2. The OHRP mailing address is as follows: Division of Compliance Oversight, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852 Phone: (301) 435-8072, Fax: (301) 402-0527.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 14.003

Title: Audits by Outside Agencies

Section: *Compliance*

Date: December 5, 2017

Reviewed: October 7, 2020

1.0 Purpose

The purpose of this SOP is to describe audits by outside agencies.

2.1 Policy

It is the policy of the IRB that the IRB will cooperate with audits by outside agencies in full accordance with regulations at Health and Human Services 45 CFR §46.

2.2 Food and Drug Administration, OHRP, Department Of Defense or National Institutes of Health Cooperative Group [Audit or Inspection]

When an IRB staff member or IRB officer is contacted by a representative from a federal agency or a National Institutes of Health cooperative group for an audit of the IRB, the following actions must be taken:

- A. Ask for the reason for the visit if this has not already been provided.
- B. Inquire what documents and information they will require during the investigation.
- C. Immediately contact the Director and the IRB Chair.
- D. An email confirming the visit will be sent to the Director, the IRB Chair, IRB staff, and the IO.
- E. When the auditor(s) arrives, ask to see the auditors' identification and business card for name and agency affiliation. Additionally, if the investigation is being conducted by a federal agency, the auditor may provide a copy of the memo from headquarters detailing the reason for the visit.
- F. During the visit, the Director and IRB Chair should be available to the auditor. A written record of the study files that are reviewed and documents photocopied must be kept.
- G. During the closing interview it is preferable that the IRB Chair, the Director and a Research Compliance Analyst be present. The Director and Analyst will note all issues identified by the investigation and the action proposed by the



auditor (if applicable).

- H. If the Director is unable to attend the exit interview, a Research Compliance Analyst will provide a summary of the results of the interview and required actions resulting from the investigation. If necessary, all individuals involved in the investigation will meet with the Director for debriefing.
- I. Following the discussion with the Director, the Analyst will immediately send an email to the individuals named in Item D above providing a synopsis of the investigation and the preliminary results presented at the closing interview. Special emphasis will be placed on those areas where deficiencies were found that require attention.
- J. The IRB Chair and Vice Chair, the Director, and the IRB staff will meet within five (5) days following the investigation to propose a corrective action plan to address deficiencies found during the investigation. The full IRB will be notified of the investigation and action plan. The full IRB may modify the plan as necessary.
- K. The Director will notify by email all principal investigators whose study files were examined during the investigation. Results from the audit that are pertinent to the specific study will be discussed. Following receipt of the official letter from the regulatory agency, the Principal Investigator will also be notified of areas of concern related to his/her study.
- L. The IRB will normally receive a report of the results of an audit. Where there are identified areas of concern or sanctions placed, the IRB Chair, Director and other appropriate UMCP officials will respond to the agency.

2.3 OHRP For-Cause Investigation of Noncompliance and Not-For-Cause Compliance Oversight Evaluation

If the IO receives notification from OHRP that OHRP has initiated a for-cause investigation of noncompliance or a not-for-cause compliance oversight evaluation, the IO, together with the IRB Chair, Director, and other appropriate institutional officials will respond immediately and appropriately with an action plan to address the matter.

2.4 Audits of Investigator's Records by Outside Agencies

When a PI is contacted by a representative from any federal agency, sponsor, or other entity



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 14.003

Title: Audits by Outside Agencies

Section: *Compliance*

Date: December 5, 2017

Reviewed: October 7, 2020

for an investigation or audit of a research protocol, the IRB must be notified of the visit. If the visit is pre-planned, an email may be sent to the Director. If it is a no-notice investigation or audit, the IRB Administrator should be called as soon as possible. The following information must be provided to the IRB:

- A. The IRB # and protocol title
- B. The name of the governmental agency, sponsor, or other entity
- C. Name of the investigator
- D. The dates of the visit
- E. The type of visit:
 1. routine surveillance/monitoring visit
 2. "for cause" investigation
 3. other: _____

Following the investigation or audit, the IRB must be notified by the Principal Investigator of any compliance issues identified during the exit interview. If the investigation or audit revealed conditions or practices that are of significant departure from the federal regulations with potential for sanctions, the IRB Chair must be immediately notified by telephone. If the IRB Chair is not available, the Director should be informed. This information will be relayed to the Director and other appropriate UMCP officials as soon as possible and HRPP Policy [#14.003](#) will be implemented as necessary.

A copy of the official letter detailing the results of the investigation must be provided to the IRB. If the investigation or audit revealed areas of concern, the Principal Investigator must provide the IRB with a copy of the response with particular emphasis on the corrective action plan.

The full IRB will be given all information and will determine what action is necessary, including reporting noncompliance to OHRP and Food and Drug Administration.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 15.001

Title: Compliance with Department of Education Regulations

Section: *Department of Education*

Date: December 5, 2017

Reviewed: October 7, 2020

1.0 Purpose

The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with Department of Education regulations.

2.1 Policy

It is the policy of the HRPP to comply with all Department of Education Policies and procedures and with the Family Educational Rights and Privacy Act (FERPA). The University of Maryland will comply with all processes and guidelines when conducting any research funded by the Department of Education.

- 2.2** The IRB will follow these guidelines when processing parental/student consent for the release or non-release of any student records for research. This responsibility may be delegated to the IRB or another individual or component of the University of Maryland, College Park (e.g., a FERPA committee).
- 2.3** An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:
- A.** Develop, validate, or administer predictive tests.
 - B.** Administer student aid programs.
 - C.** Improve instruction.
- 2.4** A school district or postsecondary institution that uses this exception of non- consent is required to enter into a written agreement with the university or investigator conducting the research that specifies:
- A.** The determination of the exception.
 - B.** The purpose, scope, and duration of the study.
 - C.** The information to be disclosed.
 - D.** That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34.99.31(a)(6) on re-disclosure and destruction of information.
 - E.** That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the university with legitimate interests.
 - F.** That the university is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
 - G.** The time period during which the university must either destroy or return the information.



**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 15.001

Title: Compliance with Department of Education
Regulations

Section: *Department of Education*

Date: December 5, 2017

Reviewed: October 7, 2020

- 2.5** Education records may be released without consent under FERPA if all personally identifiable information has been removed including:
- A.** Student's name and other direct personal identifiers, such as the student's social security number or student identification number.
 - B.** Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth and mother's maiden name.
 - C.** Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
 - D.** Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.
- 2.6** University of Maryland, College Park will follow these guidelines when conducting research that will comply with the Protection of Pupil Rights Amendment:
- 2.7** No student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:
- A.** Political affiliations.
 - B.** Mental and psychological problems potentially embarrassing to the student or his or her family.
 - C.** Sex behavior and attitudes.
 - D.** Illegal, anti-social, self-incriminating and demeaning behavior.
 - E.** Critical appraisals of other individuals with whom the student has close family relationships.
 - F.** Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.
 - G.** Religious practices, affiliations, or beliefs of the student or student's parent.
 - H.** Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.



- 2.8** University of Maryland, College Park will follow these guidelines when reviewing any IRB protocol when prior consent is used.
- A. Prior consent means:**
1. Prior consent of the student if the student is an adult or emancipated minor; or
 2. Prior written consent of the parent or guardian if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any Department of Education-funded survey, analysis, or evaluation.
- 2.9** Policies and procedures include that for research funded by the National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants.
- 2.10** For research not funded by the US Department of Education but being conducted in conjunction with the University of Maryland, the IRB will follow these guidelines:
- 2.11** The IRB must verify compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:
- A.** The right of parents to inspect, upon request, a survey created by a third party before the survey is administered or distributed by a school to students.
 - B.** Arrangements to protect student privacy in the event of the administration of a survey to students, including the right of parents to inspect, upon request, the survey, if the survey contains one or more of the same eight items of information noted above.
 - C.** The right of parents to inspect, upon request, any instructional material used as part of the educational curriculum for students.
 - D.** The administration of physical examinations or screenings that the school may administer to students.



1.0 Purpose

The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with Environmental Protection Agency regulations.

2.1 Policy

It is the policy of the HRPP to comply with all Environmental Protection Agency regulations when conducting research in conjunction with the protection of human health and the environment within Title 40 CFR.

2.2 The IRB will not approve the following when conducting research with pregnant women and children:

- A.** Research involving the intentional exposure of pregnant women, nursing women, or children to any substance.
 - 1.** EPA requires application of 40 CFR 26 Subparts C and D to provide additional protections to pregnant women and children as participants in observational research, i.e., research that does not involve intentional exposure to any substance.

2.3 The IRB will follow these guidelines when conducting research with observational behavior:

- A.** The IRB will review and approve observational research involving children that does not involve greater than minimal risk only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 40 CFR 26.406.
- B.** The IRB will review and approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual participants if the IRB find and documents that:
 - 1.** The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well-being.
 - 2.** The risk is justified by the anticipated benefit to the participants.
 - 3.** The relation of the anticipated benefit to the risk is at least as favorable to



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 15.002

Title: Compliance with Environmental Protection Agency Regulations

Section: *Environmental Protection Agency*

Date: December 5, 2017

Reviewed: October 7, 2020

the participants as that presented by available alternative approaches.

4. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 40 CFR 26.406.

2.4 The University of Maryland, College Park in conjunction with EPA policy will require submission of IRB determinations and approval to the EPA Human Subjects Research Review official for final review and approval before the research can begin.

2.5 For research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:

- A.** EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance.

EPA prohibits the intentional exposure of pregnant women, nursing women, or children to any substance.



1.0 Purpose

The purpose of this SOP is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with Department of Justice regulations.

2.1 Policy

It is the policy of the HRPP to comply with all Department of Justice regulations when conducting research within the Bureau of Prisons and/or when conducting National Institute of Justice-funded research.

- A. Implementation of programmatic or operational initiatives within the Bureau of Prisons made through pilot projects are not considered to be research.

2.2 The IRB, investigators, and research staff must follow the requirements outlined in 28 CFR 512 when conducting research within the Bureau of Prisons.

- A. Adequate research design must contribute to the advancement of knowledge about corrections and all research proposals will be reviewed by the Bureau Research Review Board.
- B. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- C. The research design must be compatible with both the operation of prison facilities and protection of human participants.
- D. The investigator must observe the rules of the institution or office in which the research is conducted.
- E. Investigators who are not employees of the Bureau must sign a statement in which he or she agrees to adhere to the provisions of 28 CFR 512.

2.3 Research taking place within the Bureau of Prisons must adhere to the following participant recruitment and compensation methods:

- A. The selection of participants within any one organization must be equitable.
- B. Incentives may not be offered to help persuade inmate participants to



participate. However, soft drinks and snacks to be consumed at the study site may be offered.

- C. Reasonable accommodations such as nominal monetary compensation for time and effort may be offered to non-confined study participants who are both:
 1. No longer in the Bureau of Prisons custody; and
 2. Participating in authorized research being conducted by Bureau employees and contractors.

- D. A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be solely as a statistical research or reporting record is provided to the agency.

- E. Except as noted in the consent statement to the participant, the investigator must not provide research information that identifies a participant to any person without that participant's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.

- F. Except for computerized data records maintained at an official Department of Justice site, records that contain information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system as it may not be disclosed.

- G. If the investigator is conducting a study of special interest to the Office of Planning, Research and Evaluation (OPRE) but the study is not a joint project involving OPRE, the investigator may be asked to provide OPRE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

2.4 All research receiving National Institute of Justice (NIJ) funding must:



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 15.003

Title: Compliance with Department of Justice
Regulations

Section: *Department of Justice*

Date: December 5, 2017

Reviewed: October 7, 2020

- A. Have a Privacy Certificate approved by the NIJ Human Subjects Protection Officer.
- B. Have Employee Confidentiality Statements signed by all investigators and research staff. These Statements must be maintained by the Principal Investigator(PI).
- C. Have a confidentiality statement on the consent form stating that confidentiality can only be broken if the participant reports immediate harm to participants or others.
- D. Have the following elements of disclosure included in the informed consent document:
 1. Identification of the investigators
 2. Anticipated uses of the results of the research.
 3. A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the projects at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
 4. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.
 5. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.



1.0 Purpose

The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with Department of Defense regulations.

2.1 Policy

It is the policy of the HRPP to comply with all federal regulations when conducting, reviewing, approving, overseeing, supporting, or managing Department of Defense- sponsored human participant research. In order to ensure compliance with these regulations, the HRPP staff will review the current Department of Defense Addendum and requirements³ at the time of initial and continuing protocol review.

- A.** IRB members and HRPP staff regularly receive training that provides information necessary to facilitate the performance of assigned responsibilities. In addition, all personnel involved in conducting human participation research are required to complete training in the protection of human participants prior to engaging in human research activities. (HRPP Policy # [3.009](#) and # [2.004](#))

Individual Department of Defense (DoD) sponsored research components may require additional specific requirements. Researchers should contact their DoD project coordinator to ensure adherence to any unique requirements.

- B.** Communicating DoD specific requirements
- 1.** If the DoD sends a contract with specific requirements, the Office of Research Administration (ORA) will review the contract.
 - 2.** ORA then communicates these requirements to both the HRPP and the investigators.
 - 3.** ORA, HRPP, and the investigators work together to make sure the requirements are met.

2.2 DoD sponsored human research must adhere to the following directives:

³ Including the DoD Protection of Human Subjects 32 CFR 219, DoD Directive 3210.07, DoD Directive 3216.02, and DoD Instruction 6200.02.



UNIVERSITY OF MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 15.004

Title: Compliance with Department of Defense Regulations

Section: *Department of Defense*

Date: December 5, 2017

Reviewed: October 7, 2020

- A. Substantive amendments to approved research must undergo scientific review prior to IRB review (HRPP Policy#[3.006](#)).
 - B. Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD after the research protocol is reviewed and approved by the IRB.
 - C. When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party.
 - D. The IRB must determine that the informed consent form includes provisions for research-related injury follows the requirements of the DoD component.
- 2.3** Investigators conducting research in foreign countries must:
- A. Have permission to conduct research in that country by certification or through a local ethics review; and
 - B. Follow all local laws, regulations, customs, and practices.
- 2.4** For research involving greater than minimal risk (as defined in 32 CFR 219.102(i), reference (c)) an independent medical monitor shall oversee a Data and Safety Monitoring Plan. In some instances, the IRB may require the development of a Data and Safety Monitoring Plan for research involving no more than minimal risk (HRPP policy #[3.010](#)).
- A. The independent medical monitor shall be appointed by name.
 - B. The research monitor has the authority to:
 - 1. Stop a research study in progress
 - 2. Remove individuals from study.
 - 3. Take any steps to protect the safety and wellbeing of participants until the IRB can assess the situation.
- 2.5** When following a DoD Addendum and when research involves U.S. military personnel, the following procedures shall be followed in order to protect military research participants in order to minimize undue influence:
- A. Officers are not permitted to influence the decision of their subordinates.
 - B. Officers and senior non-commissioned officers may not be present at the time of recruitment.
 - C. Officers and senior non-commissioned officers have a separate opportunity to participate.
 - D. When recruitment involves a percentage of a unit, an independent ombudsman shall



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 15.004

Title: Compliance with Department of Defense Regulations

Section: *Department of Defense*

Date: December 5, 2017

Reviewed: October 7, 2020

be present.

- E. When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
 - 1. An individual shall not receive pay or compensation for research conducted during duty hours.
 - 2. U.S. military personnel may be compensated for research if the participant is involved in the research when not on duty.
- 2.6** The following guidelines will be followed when considering approval of waived consent:
- A. The IRB may waive the consent process if the research participant(s) do not meet the definition of “experimental participant”
 - B. If the research participant meets the definition of “experimental participant,” the waiver of consent shall not be granted by the IRB unless approval is obtained from the Secretary of Defense.
 - C. “Experimental participant” as defined in Department of Defense Directive 3216.02 shall include:
 - 1. An individual participating in an activity for research purposes where there is an intervention or interaction for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f), reference (c)). Examples of interventions or interactions include, but are not limited to a physical procedure, a drug, a manipulation of the subject or subject's environment, or the withholding of an intervention that would have been undertaken if not for the research purpose. This does not include:
 - a. Activities carried out for purposes of diagnosis, treatment, or prevention of injury and disease in members of the Armed Forces and other mission essential personnel under Force Health Protection programs of the Department of Defense.
 - b. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions.
 - c. Monitoring for compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units. This includes such activities as drug testing, occupational health and safety monitoring, and security clearance reviews.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 15.004

Title: Compliance with Department of Defense
Regulations

Section: *Department of Defense*

Date: December 5, 2017

Reviewed: October 7, 2020

d. Activities exempt under 32 CFR 219 (reference (c)).

2.7 The IRB shall maintain a complete set of materials relevant to the review of the research protocol for a period of time sufficient to comply with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.

A. Contingent on the terms and conditions of the DoD award, the IRB may submit a copy of these materials to the DoD for archiving.

2.8 Reporting Non-compliance to the DoD

A. Incidents of noncompliance will be reviewed according to HRPP Policy [14.002](#).

B. All noncompliance determined by the Chair or Director to be serious or continuing noncompliance will be reported to OHRP and the DoD.

1. Within five (5) business days of the full board decision, the IO will send a formal letter to the OHRP Director for Compliance Oversight and DoD. The letter must include the following:

- a. Identification of the protocol.
- b. Funding of the protocol (federally or non-federally funded, commercially sponsored).
- c. Timeline and description of noncompliance.
- d. Copy of the IRB application and applicable consent document(s).
- e. Applicable reports from IRB consultants.
- f. Other documentation pertaining to the event.
- g. Correction action plan approved by the full IRB.



1.0 Purpose

The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with the Department of Energy principles for the protection of human subjects involved in Department of Energy research.

2.1 Policy

It is the policy of the HRPP to comply with all Department of Energy (DOE) regulations when conducting research in the physical sciences in conjunction with human subjects.

2.2 In addition to traditional biomedical and clinical studies, such Department of Energy human subject research includes but is not limited to the following:

- A.** Research using humans to examine devices, products, or materials with the express purpose of investigating human-machine interfaces or evaluating environmental alterations when humans are the subjects being tested;
- B.** Research using personally identifiable bodily materials such as cells, blood, tissues, urine, or hair, even if the materials were collected previously for a purpose other than the current research;
- C.** Research that collects and uses personally identifiable information such as genetic information or medical and exposure records, even if the information was collected previously for a purpose other than the current research;
- D.** Research that collects personally identifiable data, surveys, or questionnaires through direct intervention or interaction with individuals; and
- E.** Research that searches for generalizable knowledge about categories or classes of subjects (e.g., linking job conditions of worker populations to hazardous or adverse health outcomes).

2.3 Department of Energy human subject research do not include the following:

- A.** Research that hopes to improve the safety or execution of procedures that apply to routine occupational activities;
- B.** Research for occupational health surveillance of DOE Federal and contractor employees to determine apparent departures from typical health status and not for the purpose of obtaining generalizable knowledge; and
- C.** Research that involves employee surveys used as management tools to improve worker or contractor performance as long as the identity of the participant is



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 15.005

Title: Compliance with Department of Energy
Regulations

Section: *Department of Energy*

Date: December 5, 2017

Reviewed: October 7, 2020

protected.

- 2.4** The IRB will review and approve the DOE Requirements Checklist⁴ to verify Department of Energy funded research involving human subjects are in compliance with the following:
- A.** Protection of human subjects in compliance with the protection of personally identifiable information (PII).
 - B.** Protection of human subjects in compliance with CFR 46 subparts A, B, and C.

⁴ <https://science.energy.gov/ber/human-subjects/regulations-and-requirements/>



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 16.001

Title: Conflict of Interest Management

Section: *Institutional Conflict of Interest*

Date: December 5, 2017

Reviewed: October 7, 2020

1.0 Purpose

The purpose of this SOP is to describe the process to identify and manage financial conflicts of interest related to the Human Research Protection Program (HRPP) of university covered persons as defined in University of Maryland Board of Regents Policy [3.10(A), (B), & (C)].

2.1 Policy

It is the policy of the HRPP to prevent financial conflicts of interest that interfere with human research taking place at the University of Maryland, College Park (UMCP) in compliance with University of Maryland Board of Regents Policy [3.10(A), (B), & (C)].

- A. The Research Compliance Office will review disclosures that describe outside activities and interests made by researchers, as well as the responses to the conflict of interest questions for all researchers that pertain to each active IRB protocol.
- B. Should there be any investigators or project personnel with a conflict of interest, the Chair of the Conflict of Interest in Research Committee (CIRC) along with the Chair of the Institutional Review Board will be notified. A management plan will be developed to manage, reduce or eliminate the perceived, potential or real conflict of interest by the CIRC in accordance with the UMCP Conflict of Interest in Research Policy. The researcher and the Chair of the Institutional Review Board will attend this meeting to provide input in the development of this plan regarding human subject protections. In addition, the Chair of the CIRC will attend the IRB meeting where the protocol is reviewed in order to explain the background of the individual conflict of interest, provide greater detail regarding the management plan, and to address any concerns. The IRB then will vote to determine whether the management plan ensures independence of the conduct of human participant research from the interests of the researchers. If the vote is negative, the plan will be referred back to the Conflict of Interest in Research Committee for further modification, until a management plan that is acceptable to the CIRC and IRB is developed.



UNIVERSITY OF
MARYLAND

Human Research Protections
Policies and Procedures
Research Compliance Office
Institutional Review Board

Policy #: 16.002

Title: Institutional Conflict of Interest

Section: *Institutional Conflict of Interest*

Date: December 5, 2017

Reviewed: October 7, 2020

1.0 Purpose

The purpose of this SOP is to describe the management of Institutional Conflict of Interest for the University of Maryland as it relates to human subjects research.

2.1 Policy

- A. This policy governs institutional conflicts of interest at the University and applies to University Officials. This policy does not govern situations in which individuals who are not University Officials (i.e., faculty, staff, and students) might realize financial gain from the conduct of research or performance of other responsibilities at the University; the University's Conflict of Interest Committee, using existing policies and procedures, adequately identifies such situations and independently manages their associated risks to scientific objectivity and proper treatment of human and animal subjects
- B. It is critical to the mission and reputation of the University to maintain the public's trust. Because of numerous and complex relationships with public and private entities, the University must be aware of any relationships involving financial gain that may compromise or appear to compromise its integrity. The University shall establish and maintain an oversight process to manage, reduce, or eliminate institutional conflicts of interest.
- C. The ICOI Committee is also responsible for reviewing the University's investment structure, policies and procedures annually and determining whether they adequately address the identification, disclosure, and management of institutional conflicts of interest. If the ICOI Committee determines that changes are required, the ICOI Committee makes appropriate recommendations to the Vice President for Research who then consults with the President.
- D. The ICOI Committee reviews each disclosed financial interest for the potential to appear to affect any of the following: objectivity, independence and integrity of research; safety of human and animal subjects; objectivity, independence and integrity of teaching; objectivity and independence of outreach activities; appropriate use and allocation of university resources; and objectivity and independence in business and contracting decisions.



UNIVERSITY OF
MARYLAND

**Human Research Protections
Policies and Procedures**
Research Compliance Office
Institutional Review Board

Policy #: 16.002

Title: Institutional Conflict of Interest

Section: *Institutional Conflict of Interest*

Date: December 5, 2017

Reviewed: October 7, 2020

The Report of the ICOI Committee will be sent to the VPR who will review the report and recommendations of the ICOI Committee and forward them to the President to determine a course of action. In instances where the President has an Institutional Conflict of Interest, he or she must recuse himself or herself and defer to the Chancellor of the University System of Maryland who will review, create and approve management plans in consultation with the Vice President for Research